

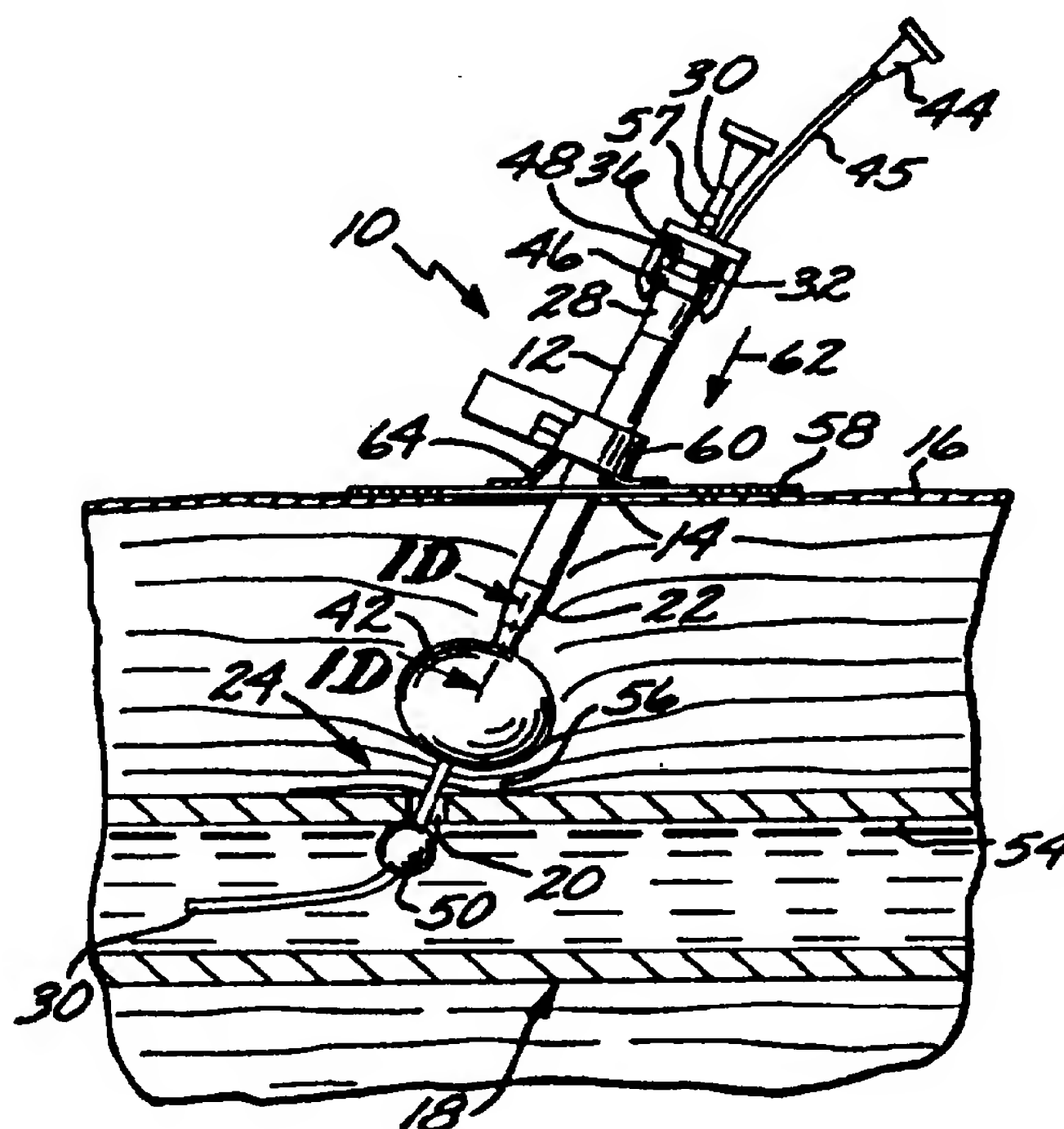
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(54) Title: APPARATUS AND METHOD FOR PERCUTANEOUS SEALING OF BLOOD VESSEL PUNCTURES**(57) Abstract**

A device for promoting hemostasis in a blood vessel puncture is employed with an introducer that accesses the puncture through an incision. The introducer has an open distal end positionable at the puncture, an external portion with an open proximal end, and an axial channel therebetween. The device includes a hollow catheter, dimensioned to pass through the introducer channel, having a distal end to which is attached an expansible compression element, which may be an inflatable balloon, a collapsible prong assembly, or a resilient foam pad. Pressure is applied to the compression element through the introducer to promote hemostasis by the compression of subcutaneous tissue adjacent the puncture. The device preferably includes a locator member passing through the catheter and into the blood vessel through the puncture. The locator member may be either a guide wire, or a hollow tube with a locating balloon, disposed near the portion of the tube insertable into the vessel.



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1 APPARATUS AND METHOD FOR PERCUTANEOUS
2 SEALING OF BLOOD VESSEL PUNCTURES

3 Background of the Invention

4 The present invention relates generally to the field of apparatus
5 and methods for sealing wounds in the blood vessels of humans or
6 animals. More specifically, the invention relates to a guided vascular
7 compression device for percutaneously sealing arterial or venous
8 punctures subsequent to surgical procedures, by promoting in situ
9 hemostasis.

10 A large number of medical therapeutic and diagnostic procedures
11 involve the percutaneous introduction of instrumentation into a vein or
12 artery. For example, percutaneous transluminal coronary angioplasty
13 (PTCA), most often involving access to the femoral artery, is performed
14 hundreds of thousands of times annually, and the number of other such
15 vessel-piercing procedures performed, e.g., percutaneous coronary
16 angiography and atherectomy, has exceeded two million per year.

17 In each event, the closing and subsequent healing of the resultant
18 vascular puncture is critical to the successful completion of the
19 procedure. Traditionally, the application of external pressure to the
20 skin entry site by a nurse or physician has been employed to stem
21 bleeding from the wound until clotting and tissue rebuilding have sealed
22 the perforation. In some situations, this pressure must be maintained
23 for half an hour to an hour or more, during which the patient is
24 uncomfortably immobilized, often with sandbags and the like. With
25 externally applied manual pressure, both patient comfort and
26 practitioner efficiency are impaired. Additionally, a risk of hematoma
27 exists since bleeding from the vessel may continue until sufficient
28 clotting effects hemostasis. Also, external pressure devices, such as

1 femoral compression systems, may be unsuitable for patients with
2 substantial amounts of subcutaneous adipose tissue, since the skin
3 surface may be a considerable distance from the vascular puncture site,
4 thereby rendering skin compression inaccurate and
5 thus less effective.

6 More recently, devices have been proposed to promote
7 hemostasis directly at the site of the vascular perforation. One class of
8 such puncture sealing devices features intraluminal plugs, as disclosed
9 in U.S. Patents Nos. 4,852,568 - Kensey; 4,890,612 - Kensey; 5,021,059 -
10 Kensey et al.; and 5,061,774 - Kensey. This class of device is
11 characterized by the placement of an object within the bloodstream of
12 the vessel to close the puncture.

13 Another approach to subcutaneous puncture closure involves
14 delivery of tissue adhesives to the perforation site, as disclosed in U.S.
15 Patent No. 5,383,899 - Hammerslag. Some likelihood exists of
16 introducing the adhesive so employed disadvantageously into the
17 bloodstream. U.S. Patent No. 4,929,246 - Sinofsky discloses the concept
18 of applying pressure directly to an artery, and relies on the directing of
19 laser energy through an optical fiber to cauterize the wound.

20 Yet another proposed solution to obviate the reliance on skin
21 surface pressure is disclosed in U.S. Patent No. 5,275,616 - Fowler,
22 wherein a cylindrical plug is inserted along the shaft of a catheter
23 segment extending from the skin surface to the blood vessel. The
24 catheter is then removed so that the plug can expand as fluid is drawn
25 into the plug from the vessel and surrounding tissue. Unless pressure is
26 applied, however, bleeding may occur around the plug into the
27 subcutaneous tissue. Another approach that similarly deposits a plug

1 into the tissue channel is disclosed in U.S. Patent No. 5,391,183 -
2 Janzen et al., which discloses a variety of plug delivery devices including
3 threaded plug pushers and multilegged channels. As in the other
4 disclosed methods for introducing a foreign plug into the incision, the
5 Janzen et al. plug material, generally resorbable, is not removed from
6 the patient once installed. Such permanent placement of foreign
7 material into the body may result in inflammation or scar formation in
8 the long term.

9 Furthermore, many of the prior art devices rely on tactile
10 sensation alone to indicate to the surgeon the proper placement of the
11 puncture closing instrumentation, and may require upstream clamping
12 of the blood vessel to reduce intraluminal pressure to atmospheric at
13 the puncture site.

14 As the foregoing description of the prior art demonstrates, none
15 of the heretofore proposed solutions fulfills the need for a relatively
16 simple, non-cautery apparatus and method for subcutaneously applying
17 pressure directly to the vicinity of the vessel puncture by means of a
18 pressure element that is removed from the patient once sealing of the
19 puncture is achieved. There is a further need for a puncture sealing
20 system that features use of instruments already in place at the access
21 site so that the position for possible reentry is not lost, and the time
22 required for the physician to change instrumentation is minimized.
23 There is a still further need for a system that maintains pressure on the
24 puncture site by lightweight mechanical means, thereby relieving the
25 patient from the discomfort of external compression means, and freeing
26 hospital personnel from constant surveillance of cumbersome external
27 pressure structures for the duration of the hemostasis. There is also a

1 need for a hemostatic device that can be effectively employed
2 regardless of the thickness of the tissue between the skin and the
3 puncture site, by applying localized pressure close to the puncture site,
4 rather than remote, diffused pressure to the skin surface.

5 Summary of the Invention

6 It is an object of this invention to provide a method and
7 apparatus for sealing post-surgical vascular punctures that overcome the
8 foregoing deficiencies.

9 It is a further object to apply pressure directly to the vicinity of
10 the vascular puncture access site utilizing a subcutaneous pressure
11 element that is removed permanently from the patient once hemostasis
12 is achieved.

13 It is another object to employ an introducer instrument already
14 in place at the access site to minimize instrumentation changing time,
15 and to maintain access during an initial clotting period to facilitate
16 possible reentry.

17 It is yet another object to maintain adequate hemostatic pressure
18 on an adipose or fatty tissue layer above the puncture site in order to
19 close the puncture naturally, to reduce the potential for
20 pseudo-aneurysm formation, and to maintain such pressure by
21 lightweight, non-labor intensive, mechanical means, thereby reducing
22 patient discomfort.

23 The present invention involves a method for sealing a puncture
24 site in a blood vessel, and apparatus for performing that method,
25 wherein use is made of an introducer sheath (commonly referred to in
26 the medical community as an "introducer") which is usually already in
27 place inside the puncture site when a medical practitioner has

1 completed a procedure that requires intravascular access. Locator
2 means, preferably either a locator tube (having an inflatable locating
3 balloon), or a standard guidewire, is passed through the introducer and
4 into the lumen of the vessel.

5 A semi-rigid catheter, including an expandable compression
6 element at its distal end, and either two axial lumens (used in a
7 compression balloon embodiment) or a single axial lumen (used in
8 other embodiments), is inserted along the locator means fully into the
9 introducer so that the expandable compression element at the distal
10 end of the catheter is contained in an unexpanded state within the
11 distal end of the introducer when the introducer is in a first or distal
12 position relative to the catheter.

13 The introducer and the catheter are partially withdrawn together
14 (moved proximally) from the puncture site until a preferred location
15 above the vessel is achieved, the relative axial positions of the
16 introducer and the catheter remaining unchanged, so that the
17 introducer remains in its first or distal position relative to the catheter.
18 This location is chosen to provide for a layer of fatty tissue above the
19 puncture site between the compression element and the vessel. The
20 extent of partial withdrawal is determined by the tactile sense of the
21 practitioner, aided by a marker on a locator tube for the embodiment
22 employing a locating balloon as the locator means, or by fluoroscopic
23 viewing of a contrast medium, for the embodiment employing a
24 guidewire as the locating means.

25 When the location is achieved, the introducer is moved to a
26 second or proximal position relative to the catheter until the
27 expandable compression element is revealed and expanded to bear on

1 the fatty tissue layer.

2 In another embodiment, the expandable compression element
3 comprises an expandable prong assembly including a resilient spanning
4 sheet for compressing the fatty tissue layer. In still another
5 embodiment, the expandable compression element comprises a foam
6 pad element bearing directly on the fatty tissue layer upon expansion
7 when deployed from the introducer.

8 Once the compression element (balloon, prongs or foam tip) is in
9 place, a lightweight holding arrangement is employed to maintain
10 hemostatic pressure. The holding arrangement comprises an adhesive
11 skin patch and fastener strips or bands bringing downward pressure on
12 a sheath cuff clamped to the introducer. After an initial period of
13 hemostasis, (approximately one to five minutes), the locator means
14 (locator balloon tube or guidewire) is removed from the puncture and
15 the apparatus. After another five to twenty-five minutes of pressure on
16 the puncture, the expandable distal end element (compression balloon,
17 prongs or foam) is collapsed, and the introducer and catheter are
18 permanently removed from the patient.

19 These and other features and advantages of the present invention
20 will be more readily apparent from the Detailed Description that
21 follows.

22 Brief Description of the Drawings

23 Fig. 1 is an elevational view, partially in cross section, illustrating
24 a first preferred embodiment of the present invention;

25 Fig. 1A is an elevational view, partially in cross section,
26 illustrating the initial position in a puncture site of the distal portion of
27 the apparatus of Fig. 1;

1 **Fig. 1B** is an elevational view, partially in cross section,
2 illustrating the apparatus of Fig. 1A in a preferred operational position;

3 **Fig. 1C** is an elevational view, partially in cross section,
4 illustrating the apparatus of Fig. 1A with the compression balloon
5 revealed and not yet inflated;

6 **Fig. 1D** is a cross sectional view taken along lines 1D-1D of Fig.
7 1, illustrating the dual lumen configuration of a catheter element of the
8 apparatus of Fig. 1;

9 **Fig. 2** is an elevational view, partially in cross section, of a second
10 preferred embodiment of the present invention, showing the
11 compression mechanism of this embodiment in a retracted state near a
12 vascular puncture site;

13 **Fig. 2A** is a perspective view of the embodiment of Fig. 2,
14 showing the compression mechanism in an expanded state;

15 **Fig. 2B** is a view similar to that of Figure 2, showing the
16 compression mechanism deployed, in its expanded state, at a vascular
17 puncture site;

18 **Fig. 3** is an elevational view, partially in cross section, of a third
19 preferred embodiment of the present invention, showing the
20 compression mechanism of this embodiment in a retracted state near a
21 vascular puncture site;

22 **Fig. 3A** is a view, similar to that of Fig. 3, illustrating the
23 compression mechanism in an expanded state;

24 **Fig. 4** is a perspective view of a fourth preferred embodiment of
25 the present invention;

26 **Fig. 4A** is an elevational view, partially in cross section,
27 illustrating the initial position in a puncture site of the introducer and

1 guidewire elements of the apparatus of Fig. 4;

2 **Fig. 4B** is a view similar to that of Fig. 4A, but showing a a
3 catheter contained within introducer when the introducer is in a first
4 axial position relative to the catheter;

5 **Fig. 4C** is an elevational view, partially in cross section,
6 illustrating the apparatus of Fig. 4A in a preferred operational position;

7 **Fig. 4D** is an elevational view, partially in cross section,
8 illustrating the apparatus of Fig. 4A with the compression balloon
9 revealed and not yet inflated, the introducer having been moved to a
10 second axial position relative to the catheter;

11 **Fig. 4E** is a perspective view, partially in cross section, illustrating
12 the compression balloon of the apparatus of Fig. 4D in an inflated
13 state;

14 **Fig. 4F** is an elevational view, partially in cross section,
15 illustrating the apparatus of Fig. 4E with the guidewire element
16 withdrawn; and

17 **Fig. 5** is an elevational view, partially in cross section, illustrating
18 a modification of the embodiment of Fig.1.

19 Detailed Description of the Preferred Embodiments

20 1. Structure of the Apparatus

21 A percutaneous blood vessel sealing device, or percutaneous
22 hemostatic device 10, which applies hemostatic sealing pressure directly
23 to tissue adjacent a vascular puncture site, without employing implanted
24 materials, is shown in Fig. 1.

25 In each exemplary embodiment described herein, an introducer
26 sheath ("introducer") 12, well known in the art, is present in an incision
27 14 that extends from the skin surface 16 to a blood vessel (artery or

1 vein) 18 of a patient at the site of a blood vessel puncture 20. The
2 introducer 12 has normally been inserted previously to provide access to
3 the vessel 18 for instrumentation (not shown) used in performing a
4 vascular procedure immediately preceding the need to seal the puncture
5 20. The initial position of an introducer 12 so inserted is most clearly
6 illustrated in Fig. 4A, which shows a tapered distal end 22 of the
7 introducer 12 at a puncture site 24, inserted within a vascular puncture
8 20. Typically, the introducer 12 will have a size of approximately 7
9 French (2.3 mm in diameter), and a length of approximately 130 mm,
10 although a size as large as 14 French (4.7 mm in diameter) may be used
11 for larger punctures.

12 A working channel 26, best seen in Fig. 1D, extends axially from
13 the proximal end 28 of the introducer 12 through its tapered distal end
14 22. In the first preferred embodiment of Figures 1 through 1D, a
15 hollow locator tube 30 extends coaxially through the introducer 12 and
16 into the vessel 18 through the puncture 20. Guided by the locator tube
17 30 into the introducer working channel 26 is a semi-rigid catheter 32
18 having a catheter proximal end 33, and a catheter distal end 34 (Fig.
19 1A). The introducer 12 is movable axially with respect to the catheter
20 32, and is disposed initially at a first axial position, or distal position, in
21 which the catheter distal end 34 is enclosed or sheathed within the
22 distal end 22 of the introducer 12.

23 The catheter 32 is a dual-lumen device having a first axial lumen
24 36 (Fig. 1D) which encompasses the locator tube 30 when the catheter
25 32 is inserted into the working channel 26 of the introducer 12. A
26 second axial lumen 38 is provided with an inflation orifice 40 near its
27 distal end, the inflation orifice communicating with the interior of a

1 compression balloon 42 that concentrically surrounds a portion of the
2 length of the catheter 32 extending proximally from its distal end 34.
3 The compression balloon 42 is initially enclosed, in an uninflated state,
4 within the distal end 22 of the introducer 12, as illustrated in Fig. 1A.
5 The opposite (proximal) end of the second axial lumen 38
6 communicates with a compression balloon inflation port 44 through an
7 inflation tube 45, as shown in Figures 1 and 4. Overall, the catheter 32
8 has an outer diameter sufficiently small to be freely insertable into the
9 introducer 12, and a length that is greater than that of the introducer
10 12, i.e., in the range of about 130 mm to about 750 mm.

11 At the proximal end 28 of the introducer 12 is a well-known luer
12 type lock fitting 46 configured to mate with a catheter proximal end
13 luer fitting 48 when the introducer 12 and the catheter 32 are in a final
14 operational position, as determined by manipulation of the locator tube
15 30, as will be described below. The locator tube 30 has an inflatable
16 intravascular locating balloon 50 at its distal end portion, shown in Fig.
17 1A in an uninflated state. The interior of the locating balloon 50 is in
18 fluid communication with the hollow interior of the locator tube 30
19 through a suitable inflation orifice (not shown), as is well known in
20 conventional balloon catheters and the like.

21 Although the luer locks 46, 48 may be employed for both the
22 locator balloon embodiment (Figures 1 through 1D) and for
23 embodiments (described below) featuring expandable compression
24 elements other than the compression balloon 42, a version using no luer
25 locks will be described below that is specifically adapted for use with
26 the compression balloon 42. Both the luer and non-luer versions are
27 suitable for embodiments employing either the inflatable locating

11

1 balloon 50 or a guidewire locating means, to be described below.

2 Returning now to Figures 1A through 1C, a progression of
3 locating positions for the device 10 is illustrated. Figure 1A shows the
4 locator tube 30, having the uninflated locating balloon 50 near its distal
5 end, inserted into the vessel 18 through the introducer 12 and the
6 vascular puncture 20. It is advantageous to construct the locator tube
7 30 so that a length of tube extends distally beyond the location of the
8 locating balloon 50 into the vessel 18 to facilitate re-access through the
9 vascular puncture 20, if required. The entire apparatus 10 (including
10 the introducer 12 and the catheter 32) is in its initial position relative to
11 the vessel; that is, the distal tip 22 of the introducer 12 is located
12 adjacent to or within the puncture 20, while the introducer 12 is in its
13 above-described first axial position or distal position relative to the
14 catheter 32, in which the catheter distal end 34 and the uninflated
15 compression balloon 42 are enclosed within the distal end 22 of the
16 introducer 12.

17 Figure 1B illustrates the device 10 after the locating balloon 50
18 has been inflated by fluid introduced into it via the locator tube 30.
19 The entire device 10 (including the introducer 12 and the catheter 32)
20 has been partially withdrawn from the puncture site 24 in the direction
21 of the arrow 52 (i.e., in the proximal direction), to a "preferred
22 operational position", in which the locating balloon 50 is lodged against
23 an interior wall 54 of the vessel 18. The introducer 12 remains in its
24 first or distal position, in which the portion of the catheter 32 carrying
25 the uninflated compression balloon 42 is enclosed within the distal end
26 22 of the introducer 12.

27 In Figure 1C, the introducer 12 has been moved axially, relative

12

1 to the catheter 32, in the direction of the arrow 52 (i.e., proximally), to
2 its second axial position, or proximal position. The movement of the
3 introducer 12 to this second or proximal position uncovers the
4 uninflated compression balloon 42.

5 The compression stage of the device 10 is illustrated next in Fig.
6 1. The compression balloon 42, inflated via the second axial lumen 38
7 (Fig. 1D), rests in an optimal position to effect natural hemostasis, viz.,
8 above a laminar portion 56 of the fatty tissue adjacent the puncture site
9 24. An optimal distance from the vessel 18 to the catheter distal end
10 34 is in the range of 2 mm to 10 mm. This distance will dispose a layer
11 of fatty tissue 56 between the vessel 18 and the catheter 32, minimizing
12 the potential for pseudo-aneurysm. The introducer luer lock 46 is
13 shown engaged with the catheter luer lock 48, assuring that a holding
14 force applied to the introducer 12 will be transmitted as well to the
15 catheter 32. In addition, a visible marker band 57 on the exterior of
16 the locating tubing 30 may advantageously be provided to align the
17 proximal ends of the introducer 12 and the catheter 32 in
18 correspondence with the location of the distal ends 22, 34 thereof when
19 the locator balloon 50 is lodged against the inner wall 54 of vessel 18.

20 An adhesive skin patch 58 with a sheath cuff 60 clamped onto
21 the external portion of the introducer 12 to apply downward force (in
22 the direction of the arrow 62, i.e., distally) on the introducer 12 is
23 shown in Figures 1 and 4. Fastener strips 64 secure the adhesive patch
24 58 to the sheath cuff 60. The fastener strips 64 may be elastic bands
25 with suitable adhesive areas, or hook and loop strips (such as the type
26 marketed under the trademark VELCRO) that adhere to areas of
27 complementary material on the patch 58. Pressure maintained by the

1 introducer sheath cuff 60 on the catheter 32 provides hemostatic
2 pressure on the compression balloon 42 to bear on the tissue layer 56
3 for a first period of time, whereupon the locating tube 30 is withdrawn
4 (the locator balloon 50 having first been deflated), and a second period
5 of time elapses, after which all instrumentation is removed from the
6 patient as will be noted when the method for sealing the puncture 20 is
7 described in detail below.

8 Another embodiment of the present invention is illustrated in
9 Figures 2, 2A, and 2B, which show a collapsible prong assembly
10 compression element 66 attached to the catheter distal end 34. The
11 prong assembly 66 is radially compressed or collapsed when enclosed
12 within the introducer 12, when the introducer is in its first or distal
13 position. The prong assembly 66 expands radially when the introducer
14 12 is partially withdrawn from the vessel 18 (Figures 2A and 2B), by
15 moving the introducer 12 to its second or proximal position in a
16 manner similar to the partial withdrawal of introducer 12 in the
17 direction of arrow 52 as described previously in connection with the
18 compression balloon embodiment.

19 The prong assembly 66 comprises a plurality of spaced-apart
20 resilient prongs 68, the proximal ends of which are attached to the
21 catheter 32, and the distal ends of which are attached to a collapsible
22 spanning film sheet or dam 70, shown expanded in Figures 2A and 2B.
23 The sheet or dam 70 allows the application of hemostatic pressure on
24 the tissue 56 above the vessel 18. A central aperture 72 in the sheet or
25 dam 70 permits the locator tube (not shown) to project through the
26 catheter 32 into the vessel 18 as described previously. Since there is no
27 compression balloon to be inflated, a catheter with a single axial lumen

14

1 36 is adequate for this application. Materials for the spanning sheet or
2 dam 70 may include polyurethane and polyethyleneterephthalate (PET).

3 Still another embodiment of the invention is illustrated in Figures
4 3 and 3A, which show a foam pad compression element 74 attached to
5 the catheter distal end 34. The foam pad element 74 is compressed
6 when enclosed within the introducer 12 when the introducer is in its
7 first or distal position. The foam pad compression element 74 then
8 expands when the introducer 12 is partially withdrawn from the vessel
9 18, as shown in Fig. 3A, by moving the introducer 12 to its second or
10 proximal position, as described above with respect to the first and
11 second embodiments. Hemostatic pressure is similarly exerted on the
12 tissue 56 above the vessel 18. An axial channel 76 in the foam pad 74
13 permits the locator tube (not shown) to project through the catheter 32
14 into the vessel 18, as described previously. As with the expanding
15 prong embodiment above, since there is no compression balloon to be
16 inflated, a catheter with a single axial lumen 36 is adequate for this
17 embodiment. Materials for the foam pad 74 may include various
18 polymeric foams, such as polyurethanes, as are well-known in the art.
19 The foam pad 74 may be impregnated with a coagulant such as
20 thrombin or protamine to effect local hemostasis.

21 The foregoing embodiments, featuring both the luer locking of
22 the introducer 12 with the catheter 32, and a variety of expandable
23 compression elements 42, 66, 74 at the catheter distal end 34, employ a
24 locator tube 30 with a locating balloon 50 to determine the optimal
25 operational location for the apparatus 10. In lieu of a locating balloon
26 50, a guidewire 78 may be utilized for the location determination of the
27 apparatus 10, as illustrated in Figures 4 through 4F.

1 In Fig. 4A, a standard guidewire 78, typically 3 French (1 mm in
2 diameter), shown coaxially located within the introducer 12, has a distal
3 end 82 extending out of the introducer distal end 22 into the puncture
4 20 of the vessel 18.

5 The catheter 32 is shown in Fig. 4B having been inserted into the
6 introducer 12 and guided to the distal end 22 of the introducer by the
7 guidewire 78. At the distal end 34 of the catheter 32 is a radiopaque
8 marker 84 for viewing under fluoroscopy, as shown in Fig. 4D.

9 Figure 4C shows an optimal location for catheter distal end 34,
10 radiopaque contrast medium (not shown) having been introduced into
11 the catheter lumen 36, and the apparatus 10 having been partially
12 withdrawn from the vessel 18 in the direction of the arrow 52 (i.e.,
13 proximally). An extravasation 85 of the radiopaque contrast medium is
14 shown marking the desired distance between the vessel 18 and the
15 catheter distal end 34, as will be explained when the method for sealing
16 the puncture is described below.

17 The introducer 12 is shown in Fig. 4D having been moved, in the
18 direction of the arrow 52, to its second or proximal position to reveal
19 the uninflated compression balloon 42 in position for inflating. Figure
20 4E illustrates the apparatus 10 with the compression balloon 42 inflated
21 and in place above the fatty layer 56 to apply hemostatic pressure for a
22 first period of time in order to effect initial closure of puncture site 24.
23 Figure 4F shows the apparatus 10 after the guidewire 78 has been
24 removed from the apparatus 10 and pressure is applied for a second
25 period of time to close the puncture 20.

26 In analogous fashion, the guidewire 78 and radiopaque
27 positioning of an expandable compression element at the distal end 34

16

1 of the catheter 32 may be employed with the prong assembly and foam
2 pad embodiments described above in connection with the locator tube
3 30. For introducing the radiopaque or contrast medium (not shown)
4 into the catheter lumen 36, a standard hemostatic "Y" 86 is used, as
5 shown in Fig. 4. The "Y" 86 has a main leg 88 for receiving the
6 guidewire 78 into the axial lumen 36 of the catheter 32, while a side
7 port 90 of the "Y" 86 is used for introducing the contrast medium into
8 the same lumen.

9 A modification of the first (compression balloon)
10 embodiment of the present invention is shown in Fig. 5, where an
11 apparatus 110 has an introducer 112 having no luer connection with a
12 catheter 132. Since the cuff 60 applies downward force in the direction
13 of the arrow 62 only to the introducer 112, and not to the catheter 132,
14 the distal end 122 of the introducer 112 must bear directly on the
15 compression balloon 42 to exert hemostatic pressure on the balloon 42.
16 Although this modification is suitable only for the compression balloon
17 embodiment of this invention, both the locator tube 30 and the
18 guidewire 78 may be utilized in this modification for optimal positioning
19 of the catheter distal end 34.

20 2. Method for Sealing Vascular Punctures

21 A brief review of a typical vascular entry procedure may be of
22 value in describing the puncture closure technique of the present
23 invention. To initiate one of the common operations such as the PTCA
24 (Percutaneous Transluminal Coronary Angioplasty) mentioned above, a
25 piercing cannula is inserted into the skin of a patient at an angle of
26 from 25 to 45 degrees until it punctures a blood vessel, e.g., the femoral
27 artery. The vessel may be located one centimeter or more beneath the

1 surface of the skin. A guidewire is inserted through the cannula into
2 the vessel, the cannula is withdrawn, and a catheter introducer sheath is
3 inserted over the guidewire into the puncture site.

4 The practitioner then uses the introducer to gain access to the
5 vascular lumen for the instrumentation used to perform the particular
6 procedure. At the conclusion of the procedure, the introducer is the
7 last device remaining in the puncture, which must then be sealed.

8 The method of the present invention provides a rapid,
9 permanent, inexpensive sealing of a puncture in a blood vessel, with no
10 foreign implants remaining in the patient. The method can be
11 understood with reference to the drawing figures and the previous
12 description of the apparatus of this invention.

13 In Fig. 1A, an introducer sheath 12 is shown in a puncture site 24
14 at the conclusion of a vascular procedure. According to one
15 embodiment of the present invention, a locator tube 30 having an
16 inflatable locating balloon 50 adjacent its distal end is inserted axially
17 through the introducer 12, into a puncture 20 and extending the
18 uninflated locating balloon 50 into the lumen of a vessel 18.

19 A dual lumen catheter 32 is passed over the locator tube 30 so
20 that a first lumen 36 (Fig. 1D) of the catheter 32 receives the locator
21 tube 30. The locator tube 30 maintains alignment of the catheter 32
22 with the puncture 20 and allows repeated access into the vessel 18, if
23 necessary. The catheter 32, having an inflatable compression balloon
24 42 at its distal end 34, is inserted fully into the introducer 12 until its
25 distal end 34, including the uninflated compression balloon 42, is at the
26 distal end 22 of the introducer 12. At this stage, the locator tube 30 is
27 pushed or pulled until a marker band 57 (shown in Fig. 1) is aligned

18

1 with the proximal end 33 of the catheter 32. The marker band 57 is
2 preselected to establish a fixed relationship with the catheter 32 so that
3 a preferred distance may be maintained between the vessel 18 and the
4 distal end 34 of catheter 32 as will be explained below. The introducer
5 12 being in its first or distal position, the uninflated compression
6 balloon 42 is fully enclosed and contained within the working channel
7 26 of the introducer 12, as described above.

8 The practitioner then inflates the locating balloon 50 via the
9 locator tube 30, partially withdrawing the introducer 12, the catheter 32
10 and the locator tube 30 from the puncture 20 in the direction of the
11 arrow 52, until the locating balloon 50 lodges against the inner wall of
12 the vessel 18 at the puncture 20, as illustrated in Fig. 1B. Since the
13 position of the catheter distal end 34 relative to the introducer distal
14 end 22 remains unchanged, the distal end 34 of the catheter is now at
15 the location predetermined by the placement of the marker band 57,
16 preferably about 5 mm to 15 mm from the puncture 20. This distance
17 will allow a layer of fatty subcutaneous tissue 56 to lie between the
18 catheter distal end 34 and the puncture 20.

19 Once the catheter distal end 34 is in the desired location, the
20 introducer 12 is further withdrawn in the direction of the arrow 52, by
21 moving it to its second or proximal position relative to the catheter 32,
22 as described above, to expose the uninflated compression balloon 42, as
23 shown in Fig. 1C. The luer fittings 46, 48 at the proximal ends of the
24 catheter 32 and the introducer 12, respectively, are now connected to
25 each other to lock the catheter 32 and the introducer 12 into a fixed
26 position relative to one another, and the compression balloon 42 is then
27 inflated, as illustrated in Fig. 1, via a second catheter lumen 38 (Fig.

1D). The compression balloon 42 is then pressed down against the fatty layer 56 above the puncture site 24, while gentle traction is maintained on the locating balloon 50, thus compressing the extravascular fatty tissue 56 between the balloons 42, 50. The fatty tissue 56 advantageously minimizes the potential of pseudo-aneurysm formation and promotes efficient hemostasis.

To assist in maintaining pressure on the vessel 18, an introducer cuff 60 is clamped onto the introducer 12 and secured to an adhesive patch 58 by means of elastic or hook and loop fastening strips 64 (Figs. 1 and 4). When the introducer 12 is locked with the catheter 32 by the luer fittings 46, 48, the downward force provided by the fastening strips 64 is transmitted from the introducer 12 through the semi-rigid catheter 32 to the compression balloon 42, maintaining hemostatic pressure on the puncture site 24 through fatty tissue 56.

After a first period of time (approximately 5 to 15 minutes), initial clotting of the puncture 20 will have occurred. The locating balloon 50 is then deflated and the locator tube 30 withdrawn from the apparatus 10, leaving only a small (e.g., approximately 1 mm in diameter) portion of the original puncture 20 to clot. The compression balloon 42 remains in place for an additional (second) period of time (approximately 5 to 25 minutes), providing hemostasis to the puncture 20, after which the compression balloon 42 is deflated and retracted proximally into the introducer 12, the luer fittings 46, 48 having first been disconnected. The sealing process having been completed, the apparatus 10 is completely removed from the patient.

The foregoing method uses an introducer 12 that is already positioned at the access site so that position is not lost in changing

1 instruments, bleeding does not occur while devices are positioned, and
2 the locator tube 30 maintains the access location for re-access if needed
3 during the initial clotting of the puncture 20. Furthermore,
4 employment of the present invention requires minimal physician time
5 and greatly reduces staff time and involvement previously devoted to
6 maintaining supradermal pressure for long periods of hemostasis. In
7 addition, the need for operating room time may be reduced by the
8 removal of the locator tube 30, the introducer 12 and the catheter 32
9 after the patient is returned to the patient's room. Overall, patient
10 discomfort is significantly lessened through the use of the foregoing
11 method as compared with the traditional manual external compression
12 techniques.

13 Similar steps are followed for implementing the method of the
14 present invention with the second embodiment of the apparatus
15 described above. In the second embodiment, the compression element
16 at catheter distal end 34 comprises the collapsible prong assembly 66, as
17 shown in Figures 2, 2A, and 2B. In this second embodiment, once the
18 introducer distal end 22 is in its initial (first or distal) position (about 5
19 to 15 mm from the vessel 18) as shown in Fig. 2, the movement of the
20 introducer 12 to its second or proximal position releases the prong
21 assembly 66 from confinement within the introducer 12, allowing the
22 individual prongs 68 of the prong assembly 66 to expand, as illustrated
23 in Fig. 2A. A resilient spanning sheet or dam 70, supported by the
24 ends of the prongs 68, then allows the application of hemostatic
25 pressure on the fatty tissue layer 56, as described earlier in connection
26 with the compression balloon embodiment. The locator tube (not
27 shown) passes through and is withdrawn from the aperture 72 in the

1 spanning film 70.

2 A third embodiment of the method, following steps substantially
3 identical to the above described procedures, involves the use of the
4 compressible foam pad 74 shown in Figs. 3 and 3A as the compression
5 element at the distal end 34 of the catheter 32.

6 In this third embodiment, when the catheter 32 is in the
7 preferred location as shown in Fig. 3, the introducer 12 is moved from
8 its first or distal position to its second or proximal position (in the
9 direction of the arrow 52) to uncover the foam pad 74, allowing it to
10 expand, as illustrated in Fig. 3A. The expanded foam pad 74 exerts
11 hemostatic pressure upon the fatty tissue layer 56, as described
12 previously. The locator tube (not shown) passes through and is
13 withdrawn from the pad channel 76 formed axially in the foam pad 74.
14 If deemed desirable by the practitioner, a coagulant agent such as
15 collagen, thrombin or protamine may be delivered to the vicinity of the
16 puncture site through the pad channel 76 which communicates with the
17 catheter axial lumen 36. Alternatively, the foam pad 74 may be
18 saturated with the agent prior to deployment.

19 The method employed with the apparatus described above may
20 also use a guidewire 78 (Fig. 4) to perform the locating functions
21 provided by the locator tube 30 in the previous embodiments. All three
22 of the compression elements, viz., the compression balloon 42, the
23 expandable prong element 66 and the foam pad 74, may be utilized
24 with the guidewire 78. For purposes of illustration, Figs. 4 through 4F,
25 showing only the compression balloon 42 alternative, may be viewed
26 with the understanding that the method to be described in conjunction
27 therewith applies to all three guidewire 78 embodiments.

22

1 Referring now to Fig. 4A, the introducer 12 is shown as it
2 remains in the puncture 20 after a vascular access procedure. A
3 conventional surgical guidewire 78 is extended through the introducer
4 12 so that its distal end 82 extends into the lumen of the vessel 18. The
5 dual lumen catheter 32 is passed over the guidewire 78 so that a first
6 lumen 36 (Fig. 1D) of the catheter 32 receives the guidewire 78. The
7 guidewire 78 maintains alignment of the catheter 32 with the puncture
8 20 and allows re-access into the vessel 18 if it becomes necessary. As
9 described earlier, the catheter 32, having an inflatable compression
10 balloon 42 at its distal end 34, is inserted fully into the introducer 12
11 until its distal end 34, including the uninflated compression balloon 42,
12 is enclosed within the working channel 26 at the distal end 22 of the
13 introducer 12, as shown in Fig.4B.

14 A radiopaque contrast medium (not shown) is introduced into
15 the catheter first lumen 36, as illustrated in Fig. 4. A main leg 88 of a
16 conventional hemostasis "Y" 86 may be passed over the guidewire 78
17 and attached to the proximal end 33 of the catheter lumen 36. The
18 contrast medium is then introduced into the catheter lumen 36 via a
19 side port 90 of the "Y" 86, and viewed by the practitioner using
20 conventional fluoroscopic techniques. To aid in locating the position of
21 the catheter distal end 34, a radiopaque marker 84 may be provided at
22 the tip of the catheter distal end 34 (Fig. 4D).

23 As the practitioner views the vascular scene under fluoroscopy,
24 the introducer 12 with the catheter 32 is partially withdrawn in the
25 direction of the arrow 52 from the puncture 20. Withdrawal is
26 continued until contrast medium in the catheter lumen 36 escaping
27 from around the guidewire 78 into the vessel 18 is observed to form an

1 extravasation cloud 85, signifying that the introducer 12 and the
2 catheter 32 have exited the puncture 20. When the practitioner is
3 satisfied through fluoroscopy that the catheter distal end element 34 is
4 the preferred distance of about 5 to 15 mm from the vessel 18,
5 withdrawal of the catheter 32 is halted, as shown in Fig. 4C.

6 The remainder of the closure procedure is essentially the same as
7 described above after the preferred position of the catheter 32 was
8 determined through the locator tube 30 method. The introducer 12 is
9 moved from its first or distal position relative to the catheter 32 to its
10 second or proximal position, to expose the uninflated compression
11 balloon 42, as shown in Fig. 4D. The compression balloon 42 is then
12 inflated to bear on the fatty tissue layer 56 as shown in Fig. 4E. The
13 locating means (in this embodiment guidewire 78) is then withdrawn
14 from the apparatus after an initial period of clotting (Fig. 4F). As
15 noted previously, the method employing the guidewire 78 may be
16 effectively adapted for use with the expandable prong element and
17 foam tip embodiments of the present invention.

18 Still another method of the invention is illustrated in Fig. 5,
19 wherein the apparatus 110 differs from the apparatus 10 in that the
20 introducer 112 and the catheter 132 are not luer-locked together.
21 Figure 5 shows the position of the catheter 132 aligned with a visible
22 marker band 57 on the locator tube 30, just as in the first embodiment
23 described above. It will be readily understood that the method of this
24 "luerless" apparatus 110 may be equally utilized with the guidewire 78
25 as with the locator tube 30 for the compression balloon embodiment of
26 this invention.

27 When the preferred location of the expanded compression

1 balloon 42 has been achieved as shown in Fig. 5, by applying either the
2 guidewire or the locator tube methods previously explained, force must
3 be applied from above to the compression balloon 42 to maintain
4 hemostatic pressure on the fatty tissue layer 56. The practitioner
5 advances the introducer 112 downward in the direction of the arrow 62
6 until the introducer distal end 22 makes contact with the surface of the
7 compression balloon 42. This hemostatic pressure is then maintained
8 by securing the introducer sheath cuff 60 to the skin patch 58 via the
9 fastener strips or bands 64. It will be noted that no downward pressure
10 is being exerted on the catheter 132 itself, since it has no mechanical
11 interlock with the introducer 112, as in the previous described
12 embodiments.

13 Although certain exemplary embodiments of the invention have
14 been described hereinabove, it will be appreciated that a number of
15 variations and modifications may suggest themselves to those skilled in
16 the pertinent arts. For example, a coagulant agent may be applied to
17 any of the above-described compression elements. Such variations and
18 modifications are considered within the spirit and scope of the
19 invention as defined in the claims that follow.

1 **WHAT IS CLAIMED IS:**

2 1. A device for promoting hemostasis in a blood vessel
3 puncture by compressing the subcutaneous tissue adjacent the puncture,
4 wherein the puncture is accessed subcutaneously through an incision by
5 an introducer disposed within the incision, the introducer having a
6 proximal portion disposed externally to the skin surface, a distal end
7 initially positionable within the puncture, and an axial channel
8 therebetween, the device comprising:

9 a catheter dimensioned to be received within the axial
10 channel and having an axial lumen communicating with an open
11 distal end, the introducer being axially movable relative to the
12 catheter between a distal position and a proximal position, the
13 distal end of the catheter being enclosed within the introducer
14 when the introducer is in its distal position, and being exposed to
15 the subcutaneous tissue distally from the distal end of the
16 introducer when the introducer is moved to its proximal position;

17 an elongate, flexible locator member extending through the
18 catheter lumen and the distal end of the catheter and having a
19 distal portion extensible into the interior of the vessel through
20 the puncture; and

21 an expansible compression element attached to the distal
22 end of the catheter, the compression element having a collapsed
23 position when the distal end of the catheter is enclosed, and an
24 expanded position when the distal end of the catheter is exposed;

25 whereby the compression element, in its expanded position,
26 is deployable so as to compress the subcutaneous tissue adjacent
27 the puncture, thereby to promote hemostasis at the puncture.

26

- 1 2. The device of Claim 1, wherein the axial lumen of the
2 catheter is a first catheter lumen, wherein the catheter includes a
3 second axial lumen, and wherein the compression element comprises:
4 an inflatable element in fluid communication with the
5 second catheter lumen and inflatable by a fluid introduced
6 through the second lumen, the compression element being in its
7 collapsed position when the inflatable element is uninflated and
8 in its expanded position when the inflatable element is inflated.
- 9 3. The device of Claim 1, wherein the compression element
10 comprises an assembly of collapsible prongs, each having a proximal
11 end attached to the distal end of the catheter, and a distal end attached
12 to a resilient spanning sheet, the compression element being in its
13 collapsed position when the prong assembly is collapsed radially
14 inwardly, and in its expanded position when the prong assembly is
15 expanded radially outwardly.
- 16 4. The device of Claim 1, wherein the compression element
17 comprises a resilient foam pad attached to the distal end of the catheter
18 and having a collapsed position when the distal end of the catheter is
19 enclosed, and an expanded position when the distal end of the catheter
20 is exposed.
- 21 5. The device of Claim 1, wherein the locator member
22 comprises:
23 a hollow locator tube disposed axially through the catheter
24 lumen so as to extend through the distal end of the catheter and
25 having a distal portion extensible into the interior of the vessel
26 through the puncture; and
27 a locating balloon disposed at the distal portion of the

1 locator tube and inflatable through the locator tube when
2 positioned in the interior of the vessel.

3 6. The device of Claim 1, wherein the locator member
4 comprises:

5 an elongate guide wire disposed axially through the
6 catheter lumen so as to extend through the distal end of the
7 catheter and into the interior of the vessel through the puncture.

8 7. The device of Claim 2, wherein the locator member
9 comprises:

10 a hollow locator tube disposed axially through the first
11 catheter lumen so as to extend through the distal end of the
12 catheter and having a distal portion extensible into the interior of
13 the vessel through the puncture; and

14 a locating balloon disposed at the distal portion of the
15 locator tube and inflatable through the locator tube when
16 positioned in the interior of the vessel.

17 8. The device of Claim 2, wherein the locator member
18 comprises:

19 an elongate guide wire disposed axially through the first
20 catheter lumen so as to extend through the distal end of the
21 catheter and into the interior of the vessel through the puncture.

22 9. The device of Claim 3, wherein the spanning sheet includes
23 an aperture, and wherein the locator member comprises:

24 a hollow locator tube disposed axially through the catheter
25 lumen so as to extend through the distal end of the catheter and
26 the spanning sheet aperture, and having a distal portion
27 extensible into the interior of the vessel through the puncture;

1 and

2 a locating balloon disposed at the distal portion of the
3 locator tube and inflatable through the locator tube when
4 positioned in the interior of the vessel.

5 10. The device of Claim 3, wherein the spanning sheet includes
6 an aperture, and wherein the locator member comprises:

7 an elongate guide wire disposed axially through the
8 catheter lumen so as to extend through the distal end of the
9 catheter and the spanning sheet aperture into the interior of the
10 vessel through the puncture.

11 11. The device of Claim 4, wherein the foam pad includes an
12 axial passage, and wherein the locator member comprises:

13 a hollow locator tube disposed axially through the catheter
14 lumen so as to extend through the distal end of the catheter and
15 the axial passage in the foam pad, the locator tube having a distal
16 portion extensible into the interior of the vessel through the
17 puncture; and

18 a locating balloon disposed at the distal portion of the
19 locator tube and inflatable through the locator tube when
20 positioned in the interior of the vessel.

21 12. The device of Claim 4, wherein the foam pad includes an
22 axial passage, and wherein the locator member comprises:

23 an elongate guide wire disposed axially through the
24 catheter lumen so as to extend through the distal end of the
25 catheter and the axial passage in the foam pad, the guide wire
26 having a distal portion extensible into the interior of the vessel
27 through the puncture.

1 13. The device of Claim 1, further comprising:
2 a radiopaque marker at the distal end of the catheter; and
3 means for introducing a contrast medium into the catheter
4 lumen.

5 14. The device of Claim 2, further comprising:
6 a radiopaque marker at the distal end of the catheter; and
7 means for introducing a contrast medium into the first
8 catheter lumen.

9 15. The device of Claim 1, further comprising:
10 pressure applying means, engageable with the external
11 portion of the introducer, for applying a downward force to the
12 introducer when the catheter is disposed within the axial channel
13 of the introducer.

14 16. The device of Claim 15, wherein the catheter is connected
15 to the introducer so that the downward force is applied to both the
16 introducer and the catheter.

17 17. The device of Claim 15, wherein the pressure applying
18 means comprises:
19 a clamping device secured to the external portion of the
20 introducer; and
21 a skin patch secured to the clamping device and adhesively
22 attachable to the surface of the skin.

23 18. The device of Claim 16, wherein the pressure applying
24 means comprises:
25 a clamping device secured to the external portion of the
26 introducer; and
27 a skin patch secured to the clamping device and adhesively

1 attachable to the surface of the skin.

2 19. A device for promoting hemostasis in a blood vessel
3 puncture by compressing the subcutaneous tissue adjacent the puncture,
4 wherein the puncture is accessed subcutaneously through an incision by
5 an introducer disposed within the incision, the introducer having a
6 proximal end disposed externally to the skin surface, a distal end
7 initially positionable within the puncture, and an axial channel
8 therebetween, the device comprising:

9 a catheter dimensioned to be received within the axial
10 channel and having a first axial lumen communicating with an
11 open distal end and a second axial lumen, the introducer being
12 axially movable relative to the catheter between a distal position
13 and a proximal position, the distal end of the catheter being
14 enclosed within the introducer when the introducer is in its distal
15 position, and being exposed to the subcutaneous tissue distally
16 from the distal end of the introducer when the introducer is
17 moved to its proximal position; and

18 an inflatable compression element attached to the distal
19 end of the catheter and in fluid communication with the second
20 lumen so as to be inflatable with a fluid introduced through the
21 second lumen when the distal end of the catheter is exposed;

22 whereby the compression element, when inflated, is
23 deployable so as to compress the subcutaneous tissue adjacent
24 the puncture, thereby to promote hemostasis at the puncture.

25 20. The device of Claim 19, further comprising:

26 an elongate, flexible locator member extending through the
27 first catheter lumen and the distal end of the catheter, and

1 having a distal portion extensible into the interior of the vessel
2 through the puncture.

3 21. The device of Claim 20, wherein the locator member
4 comprises:

5 a hollow locator tube disposed axially through the first
6 catheter lumen so as to extend through the distal end of the
7 catheter and having a distal portion extensible into the interior of
8 the vessel through the puncture; and

9 a locating balloon disposed at the distal portion of the
10 locator tube and inflatable through the locator tube when
11 positioned in the interior of the vessel.

12 22. The device of Claim 20, wherein the locator member
13 comprises:

14 an elongate guide wire disposed axially through the first
15 catheter lumen so as to extend through the distal end of the
16 catheter and into the interior of the vessel through the puncture.

17 23. The device of Claim 19, further comprising:

18 a radiopaque marker at the distal end of the catheter; and
19 means for introducing a contrast medium into the first
20 catheter lumen.

21 24. The device of Claim 19, further comprising:

22 pressure applying means, engageable with the external
23 portion of the introducer, for applying a downward force to the
24 introducer when the catheter is disposed within the axial channel
25 of the introducer.

26 25. The device of Claim 24, wherein the catheter is connected
27 to the introducer so that the downward force is applied to both the

1 introducer and the catheter.

2 26. The device of Claim 24, wherein the pressure applying
3 means comprises:

4 a clamping device secured to the external portion of the
5 introducer; and

6 a skin patch secured to the clamping device and adhesively
7 attachable to the surface of the skin.

8 27. The device of Claim 25, wherein the pressure applying
9 means comprises:

10 a clamping device secured to the external portion of the
11 introducer; and

12 a skin patch secured to the clamping device and adhesively
13 attachable to the surface of the skin.

14 28. A device for promoting hemostasis in a blood vessel
15 puncture by compressing the subcutaneous tissue adjacent the puncture,
16 wherein the puncture is accessed subcutaneously through an incision by
17 an introducer disposed within the incision, the introducer having a
18 proximal end disposed externally to the skin surface, a distal end
19 initially positionable within the puncture, and an axial channel
20 therebetween, the device comprising:

21 a catheter dimensioned to be received within the axial
22 channel and having an axial lumen communicating with an open
23 distal end, the introducer being axially movable relative to the
24 catheter between a distal position and a proximal position, the
25 distal end of the catheter being enclosed within the introducer
26 when the introducer is in its distal position, and being exposed to
27 the subcutaneous tissue distally from the distal end of the

1 introducer when the introducer is moved to its proximal position;
2 and

3 an assembly of collapsible prongs, each having a proximal
4 end attached to the distal end of the catheter and a distal end
5 attached to a spanning sheet, the prong assembly having a
6 radially inwardly collapsed position when the distal end of the
7 catheter is enclosed, and a radially outwardly expanded position
8 when the distal end of the catheter is exposed;

9 whereby the prong assembly, in its expanded position, is
10 deployable so as to compress the subcutaneous tissue adjacent
11 the puncture, thereby to promote hemostasis at the puncture.

12 29. The device of Claim 28, wherein the spanning sheet
13 includes an aperture, the device further comprising:

14 an elongate, flexible locator member extensible through
15 the catheter lumen, the distal end of the catheter, and the
16 spanning sheet aperture, and having a distal portion extensible
17 into the interior of the vessel through the puncture.

18 30. The device of Claim 29, wherein the locator member
19 comprises:

20 a hollow locator tube extensible axially through the
21 catheter lumen so as to extend through the distal end of the
22 catheter and the spanning sheet aperture, and having a distal
23 portion extensible into the interior of the vessel through the
24 puncture; and

25 a locating balloon disposed at the distal portion of the
26 locator tube and inflatable through the locator tube when
27 positioned in the interior of the vessel.

34

1 31. The device of Claim 29, wherein the locator member
2 comprises:

3 an elongate guide wire extensible axially through the
4 catheter lumen so as to extend through the distal end of the
5 catheter and the spanning sheet aperture, and into the interior of
6 the vessel through the puncture.

7 32. The device of Claim 28, further comprising:

8 a radiopaque marker at the distal end of the catheter; and
9 means for introducing a contrast medium into the catheter
10 lumen.

11 33. The device of Claim 28, further comprising:

12 pressure applying means, engageable with the external
13 portion of the introducer, for applying a downward force to the
14 introducer when the catheter is disposed within the axial channel
15 of the introducer.

16 34. The device of Claim 33, wherein the catheter is connected
17 to the introducer so that the downward force is applied to both the
18 introducer and the catheter.

19 35. The device of Claim 33, wherein the pressure applying
20 means comprises:

21 a clamping device secured to the external portion of the
22 introducer; and

23 a skin patch secured to the clamping device and adhesively
24 attachable to the surface of the skin.

25 36. The device of Claim 34, wherein the pressure applying
26 means comprises:

27 a clamping device secured to the external portion of the

1 introducer; and

2 a skin patch secured to the clamping device and adhesively
3 attachable to the surface of the skin.

4 37. A device for promoting hemostasis in a blood vessel
5 puncture by compressing the subcutaneous tissue adjacent the puncture,
6 wherein the puncture is accessed subcutaneously through an incision by
7 an introducer disposed within the incision, the introducer having a
8 proximal end disposed externally to the skin surface, a distal end
9 initially positionable within the puncture, and an axial channel
10 therebetween, the device comprising:

11 a catheter dimensioned to be received within the axial
12 channel and having an axial lumen communicating with an open
13 distal end, the introducer being axially movable relative to the
14 catheter between a distal position and a proximal position, the
15 distal end of the catheter being enclosed within the introducer
16 when the introducer is in its distal position, and being exposed to
17 the subcutaneous tissue distally from the distal end of the
18 introducer when the introducer is moved to its proximal position;
19 and

20 a resilient foam pad attached to the distal end of the
21 catheter, the pad having a collapsed position when the distal end
22 of the catheter is enclosed, and an expanded position when the
23 distal end of the catheter is exposed;

24 whereby the pad, in its expanded position, is deployable so
25 as to compress the subcutaneous tissue adjacent the puncture,
26 thereby to promote hemostasis at the puncture.

27 38. The device of Claim 37, wherein the pad includes an axial

1 passage therethrough, the device further comprising:

2 an elongate, flexible locator member extensible through
3 the catheter lumen, the distal end of the catheter and the axial
4 passage through the pad, and having a distal portion extensible
5 into the interior of the vessel through the puncture.

6 39. The device of Claim 38, wherein the locator member
7 comprises:

8 a hollow locator tube extensible axially through the
9 catheter lumen so as to extend through the distal end of the
10 catheter and the axial passage through the pad, and having a
11 distal portion extensible into the interior of the vessel through
12 the puncture; and

13 a locating balloon disposed at the distal portion of the
14 locator tube and inflatable through the locator tube when
15 positioned in the interior of the vessel.

16 40. The device of Claim 38, wherein the locator member
17 comprises:

18 an elongate guide wire extensible axially through the
19 catheter lumen so as to extend through the distal end of the
20 catheter and the axial passage through the pad, and into the
21 interior of the vessel through the puncture.

22 41. The device of Claim 37, further comprising:

23 a radiopaque marker at the distal end of the catheter; and
24 means for introducing a contrast medium into the catheter
25 lumen.

26 42. The device of Claim 37, further comprising:

27 pressure applying means, engageable with the external

1 portion of the introducer, for applying a downward force to the
2 introducer when the catheter is disposed within the axial channel
3 of the introducer.

4 43. The device of Claim 42, wherein the catheter is connected
5 to the introducer so that the downward force is applied to both the
6 introducer and the catheter.

7 44. The device of Claim 42, wherein the pressure applying
8 means comprises:

9 a clamping device secured to the external portion of the
10 introducer; and

11 a skin patch secured to the clamping device and adhesively
12 attachable to the surface of the skin.

13 45. The device of Claim 43, wherein the pressure applying
14 means comprises:

15 a clamping device secured to the external portion of the
16 introducer; and

17 a skin patch secured to the clamping device and adhesively
18 attachable to the surface of the skin.

19 46. A method for promoting hemostasis in a blood vessel
20 puncture that is accessed subcutaneously through an incision by an
21 introducer disposed within the incision, the introducer having a portion
22 disposed externally to the skin surface with an open proximal end, an
23 open distal end initially positionable within the puncture, and an axial
24 channel therebetween, the method comprising the steps of:

25 providing a catheter having a distal end to which is
26 attached an expansible compression element, and passing the
27 catheter through the introducer channel so that the compression

1 element is enclosed, in a collapsed position, near the distal end
2 of the introducer;

3 withdrawing the introducer and the catheter together in
4 the proximal direction a predetermined distance from the
5 puncture, while maintaining the compression element enclosed
6 within the introducer;

7 moving the introducer axially relative to the catheter in the
8 proximal direction to expose the compression element from the
9 distal end of the introducer;

10 expanding the compression element in the subcutaneous
11 tissue between the puncture and the skin; and

12 applying pressure to the compression element to promote
13 hemostasis at the puncture.

14 47. The method of Claim 46, further comprising the step of:
15 before the step of passing the catheter, passing an
16 elongate, flexible locator member through the introducer channel
17 and into the blood vessel through the distal end of the introducer
18 and through the puncture, the catheter having an axial lumen so
19 that, when the catheter is passed through the introducer channel,
20 the catheter is disposed coaxially between the locator member
21 and the introducer.

22 48. The method of Claim 47, wherein the locator member
23 comprises a hollow locator tube having a distal portion extensible into
24 the interior of the blood vessel through the puncture, and an inflatable
25 locating balloon disposed at the distal portion of the tube, and wherein
26 the step of withdrawing the catheter and the introducer includes the
27 steps of:

1 inflating the locating balloon through the locator tube
2 while the distal portion of the tube, including the locating
3 balloon, is disposed within the blood vessel; and

4 withdrawing the catheter, the introducer, and the locator
5 tube together in the proximal direction until the locating balloon
6 lodges against the interior wall of the blood vessel.

7 49. The method of Claim 47, further comprising the steps of:
8 after the application of pressure to the compression
9 element for a first period of time, withdrawing the locator
10 member from the puncture; and

11 continuing the application of pressure to the compression
12 element for a second period of time.

13 50. The method of Claim 49, further comprising the steps of:
14 after the second period of time has elapsed, collapsing the
15 compression element; and

16 withdrawing the catheter and the introducer from the
17 incision.

18 51. The method of Claim 47, wherein the locator member
19 includes a guide wire having a distal portion extensible into the blood
20 vessel through the puncture, and wherein the step of withdrawing
21 includes the steps of:

22 introducing a contrast medium into the puncture through
23 the catheter lumen; and

24 fluoroscopically viewing the contrast medium as the
25 catheter and the introducer are withdrawn to determine when the
26 predetermined distance from the puncture has been attained.

27 52. The method of Claim 46, wherein the step of applying

1 pressure to the compression element comprises the steps of:
2 applying pressure to the external portion of the introducer;
3 and
4 transmitting the pressure to the compression element.
5 53. The method of Claim 52, wherein the transmitting step
6 comprises the steps of:
7 attaching the introducer to the skin surface;
8 connecting the introducer to the catheter; and
9 transmitting the pressure from the introducer to the
10 catheter and then to the compression element.

FIG. 1

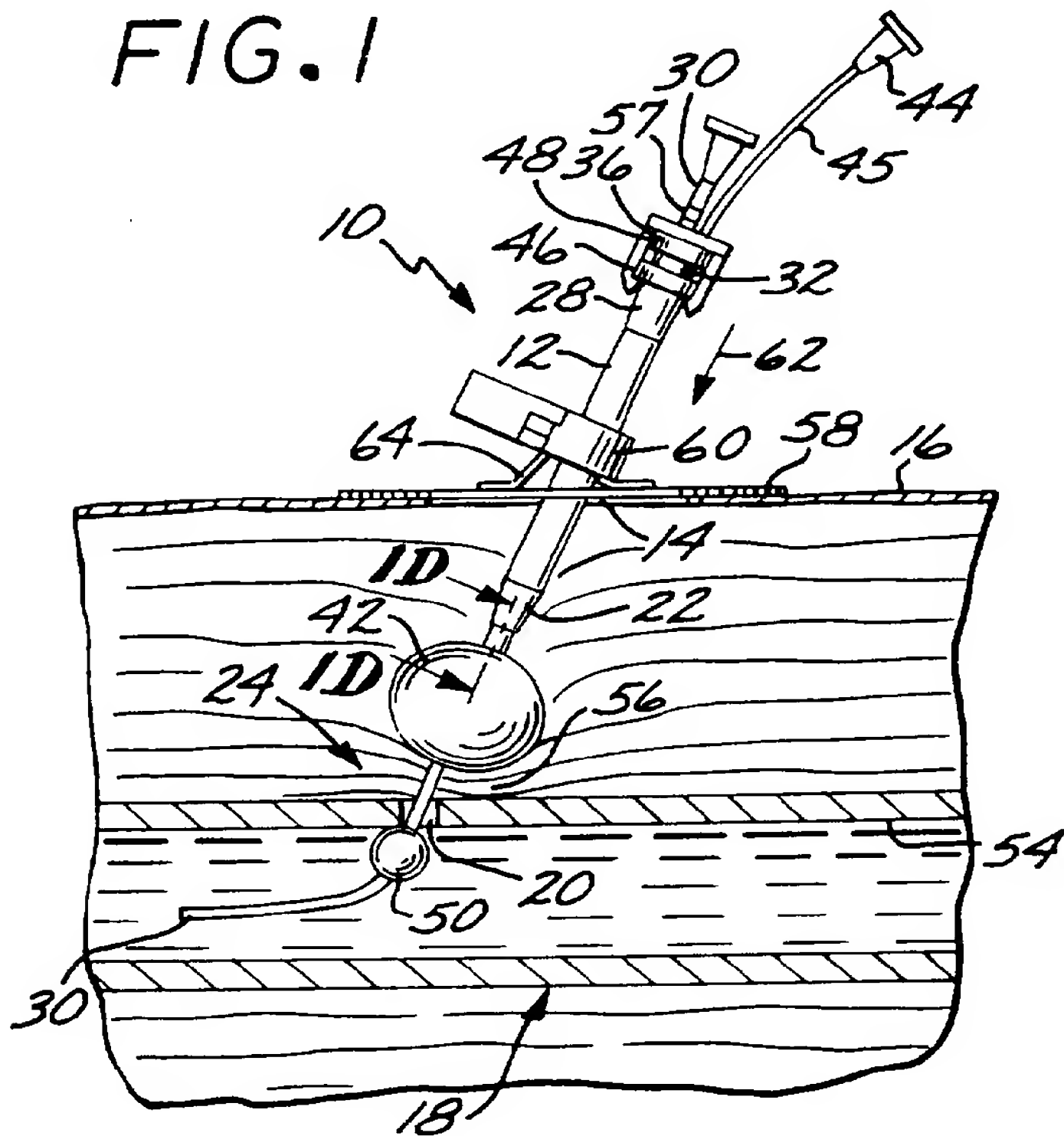


FIG. 1A

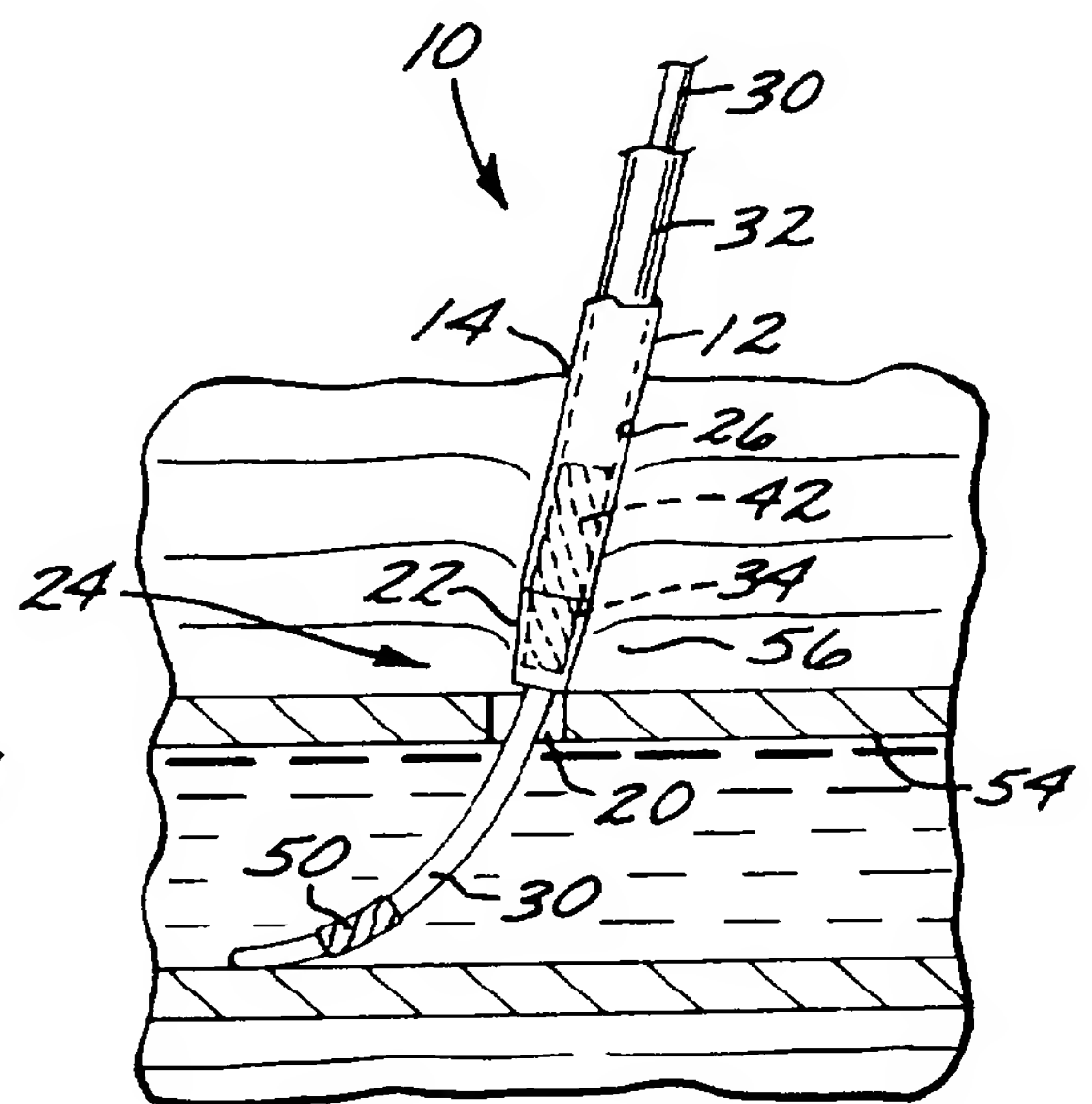


FIG. 1B

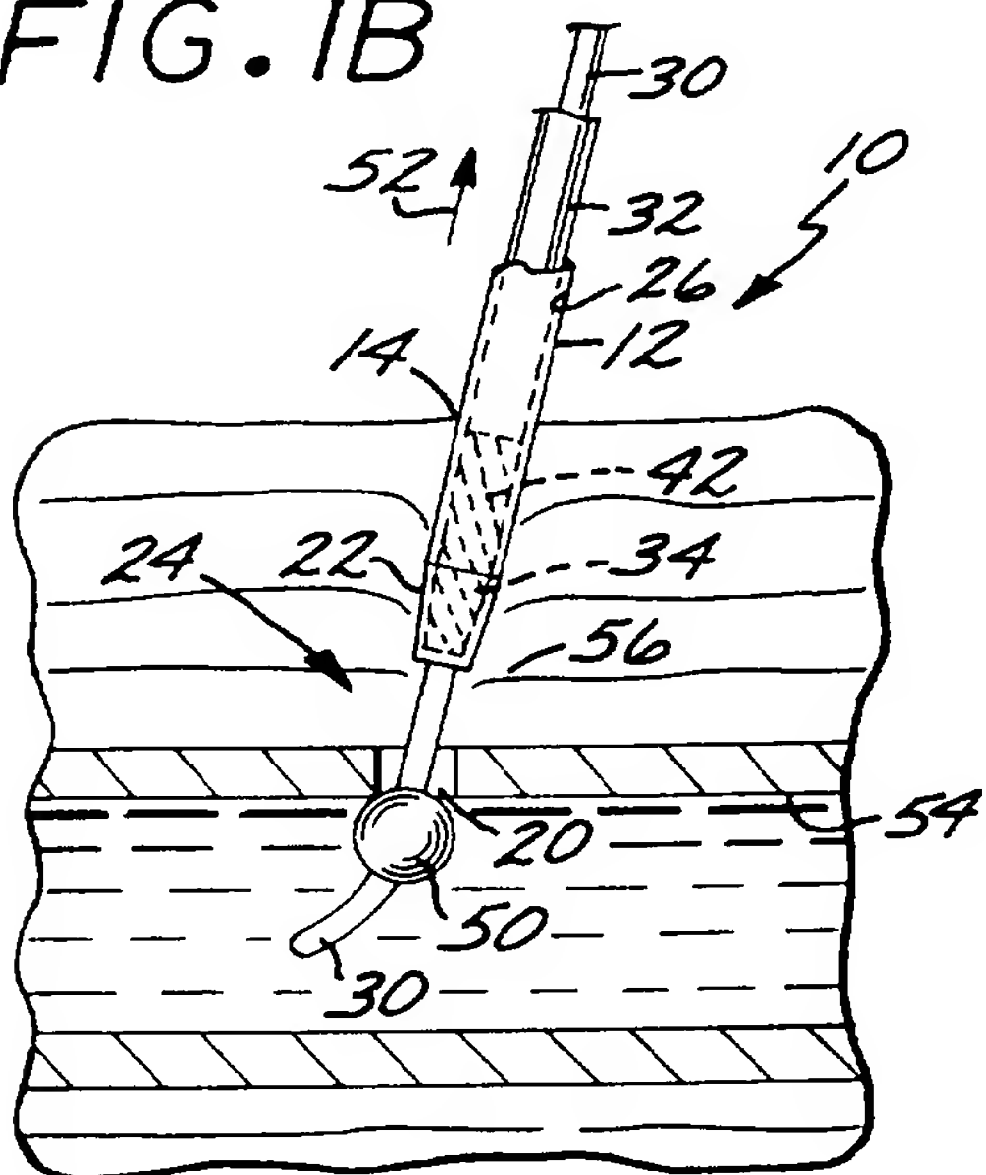
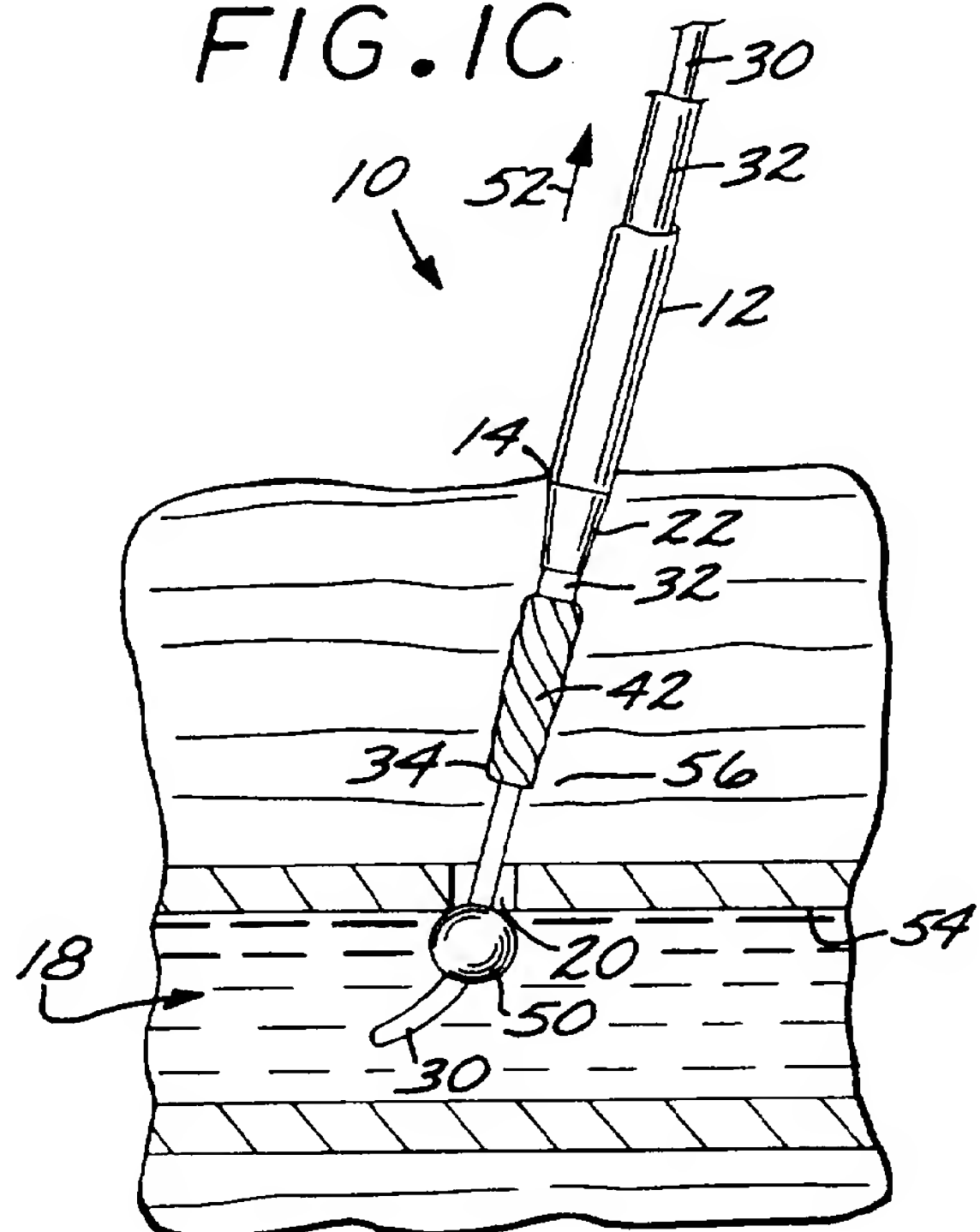
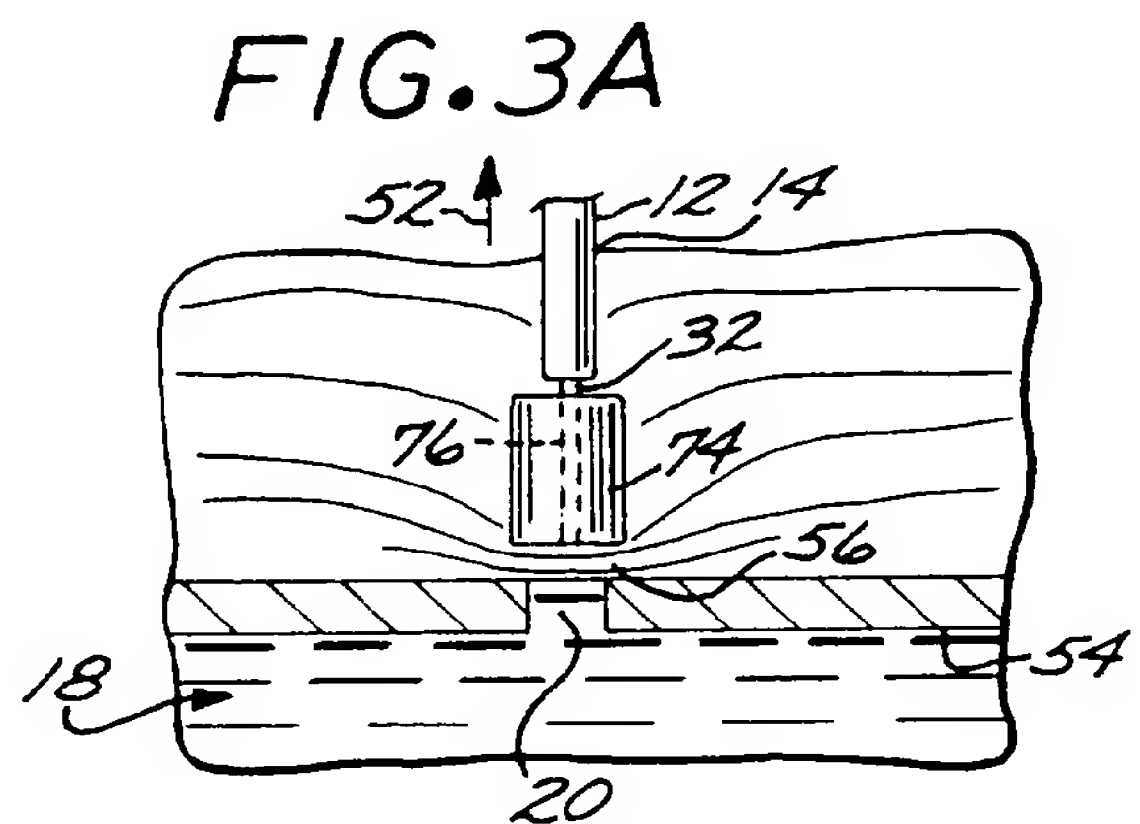
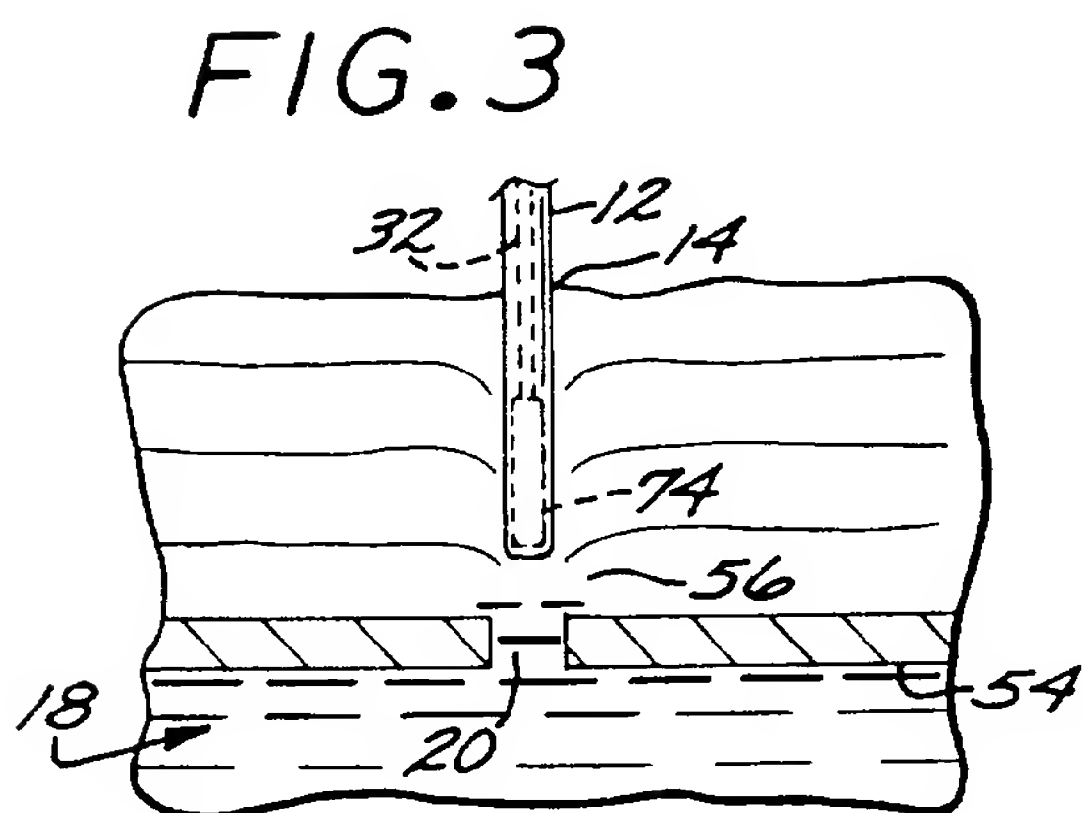
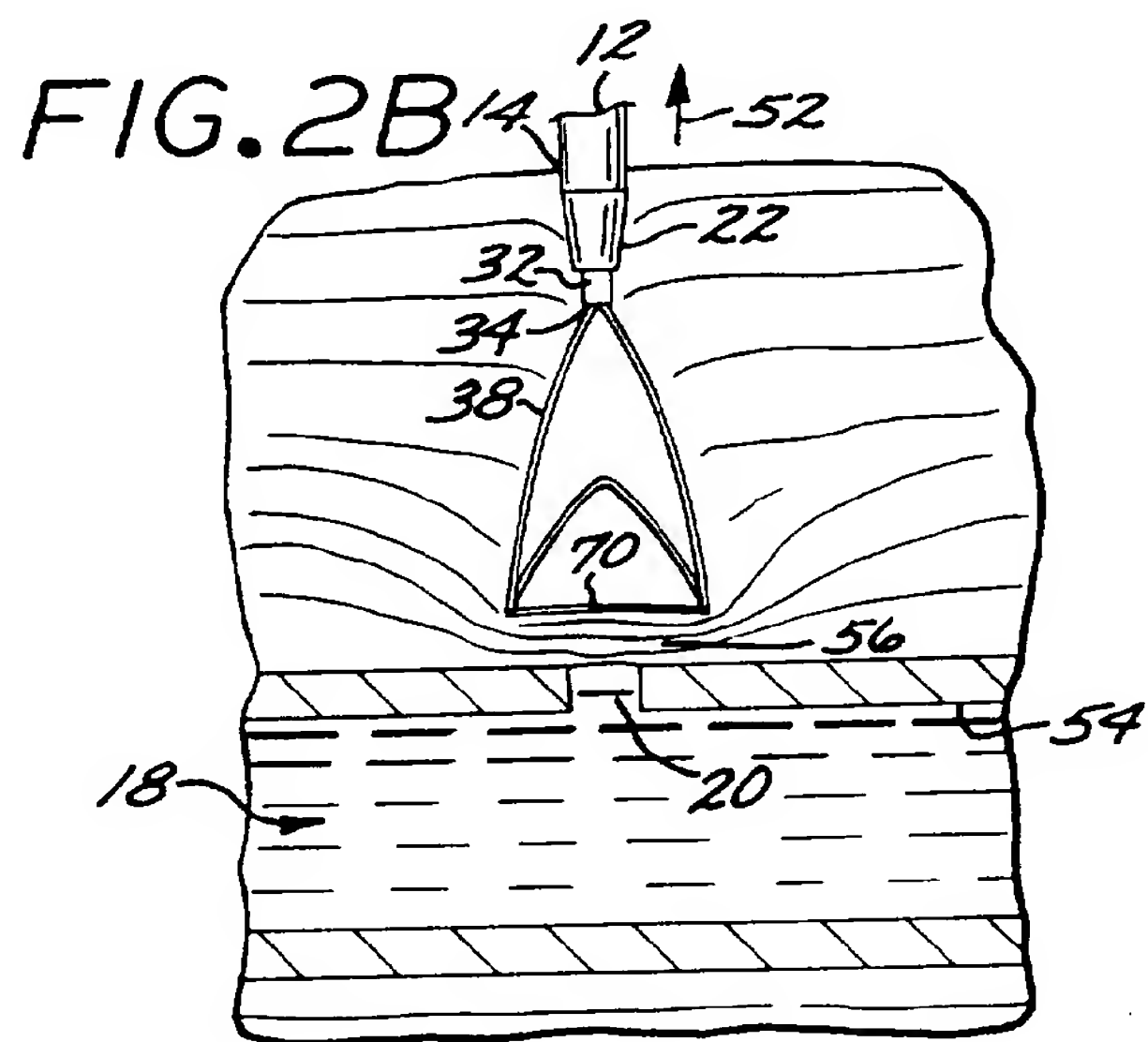
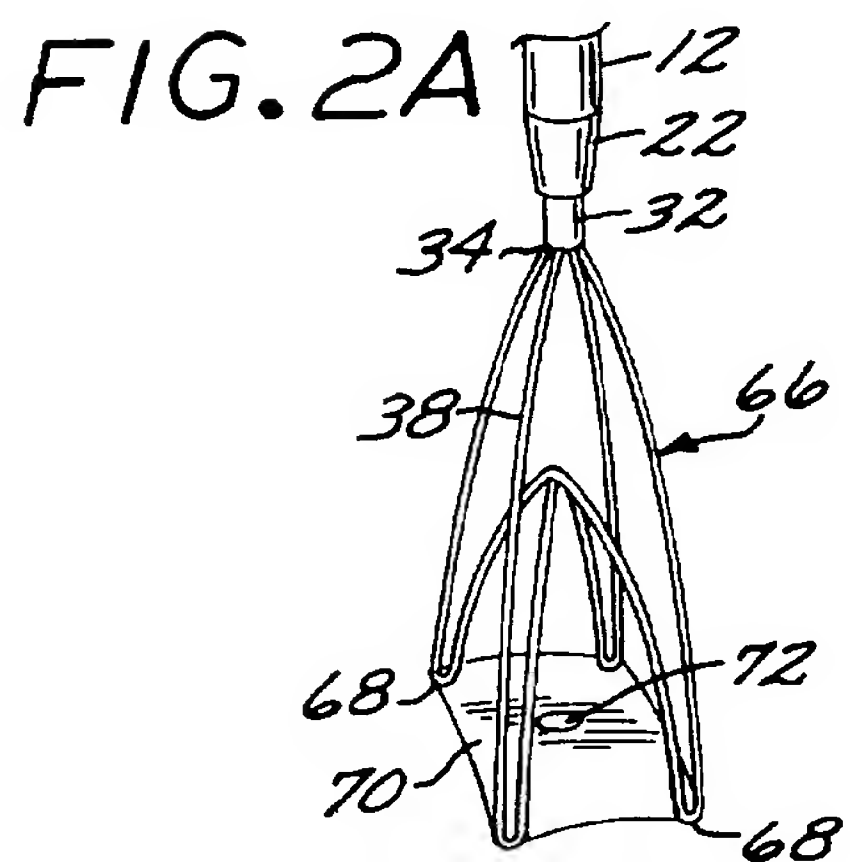
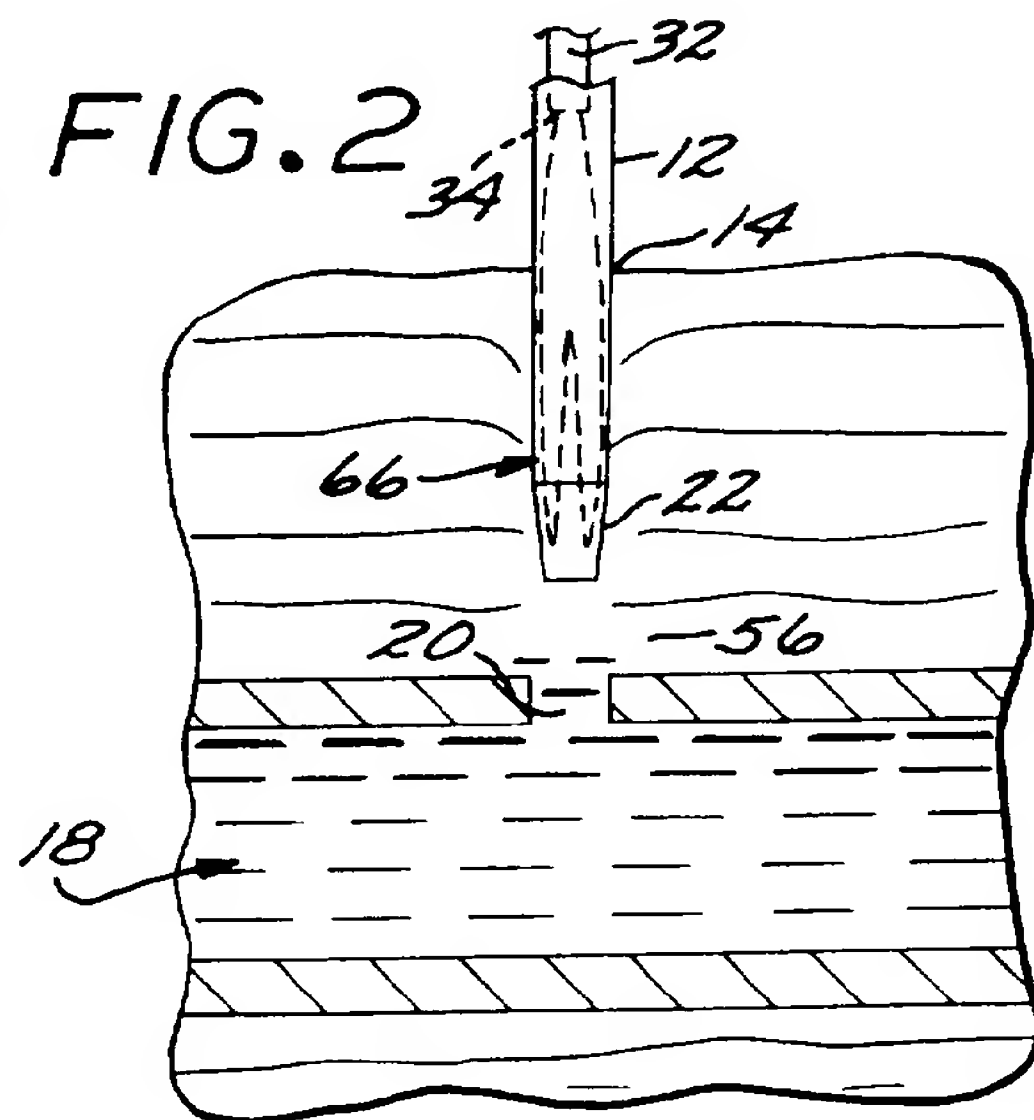
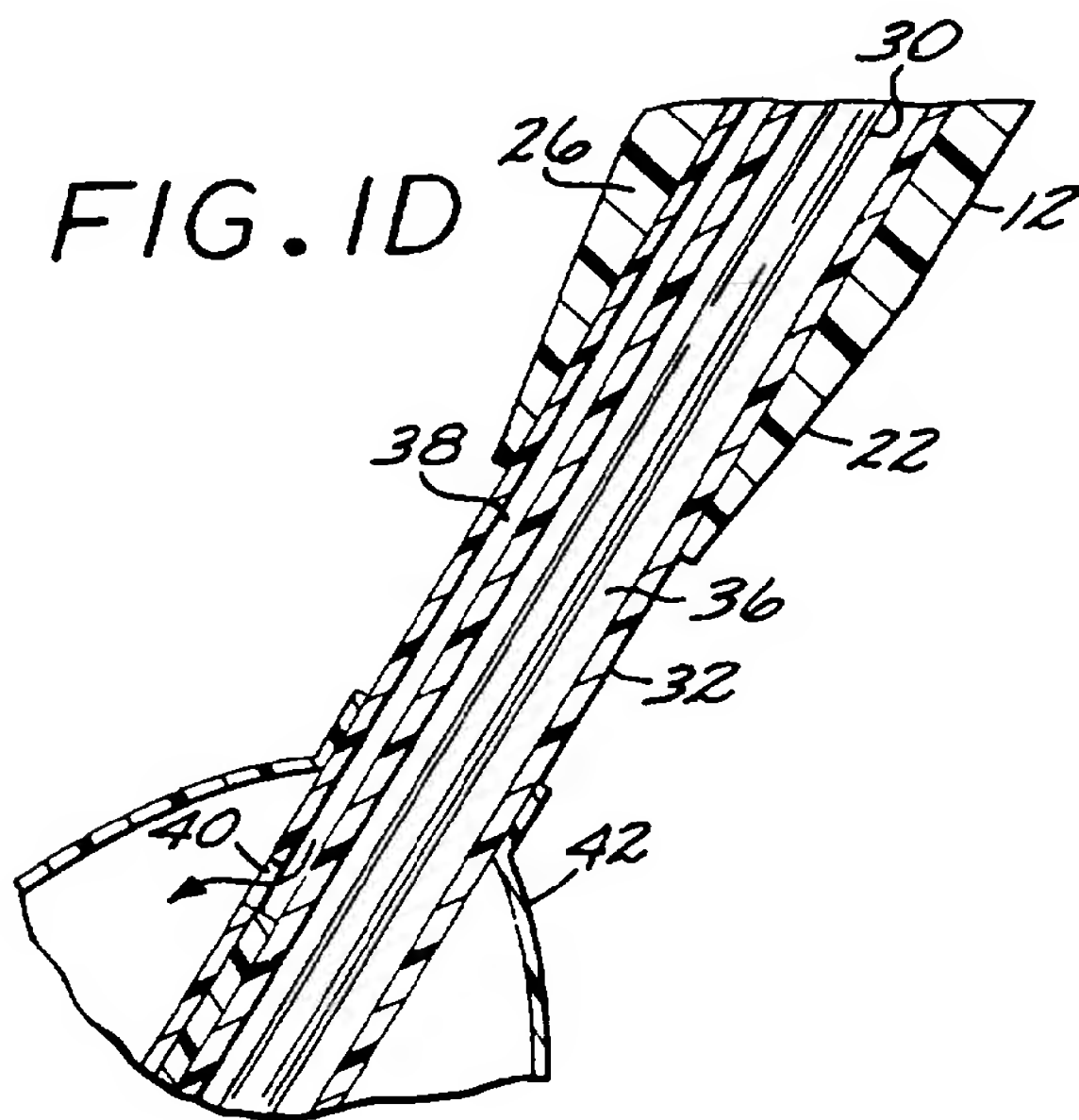


FIG. 1C





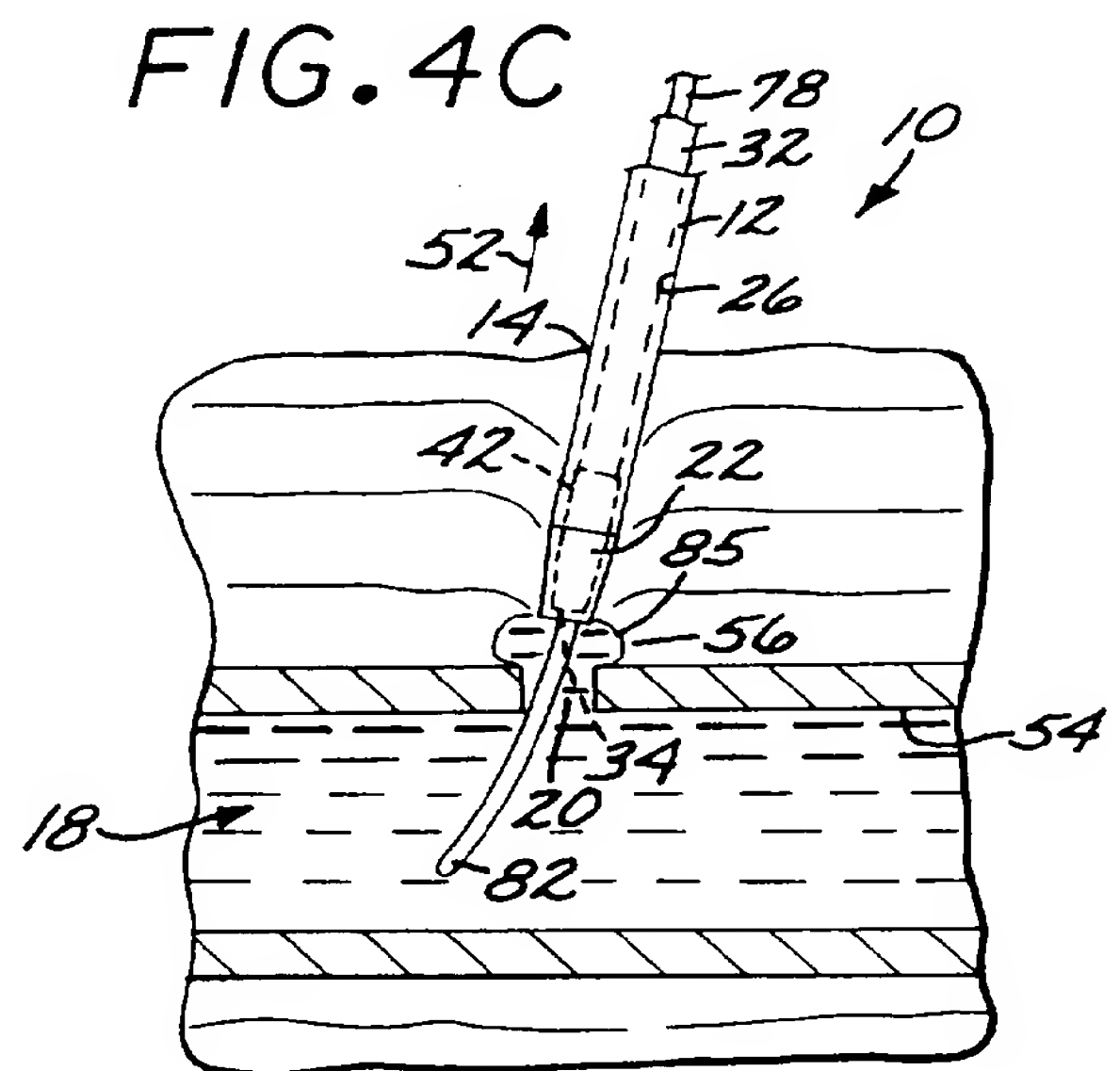
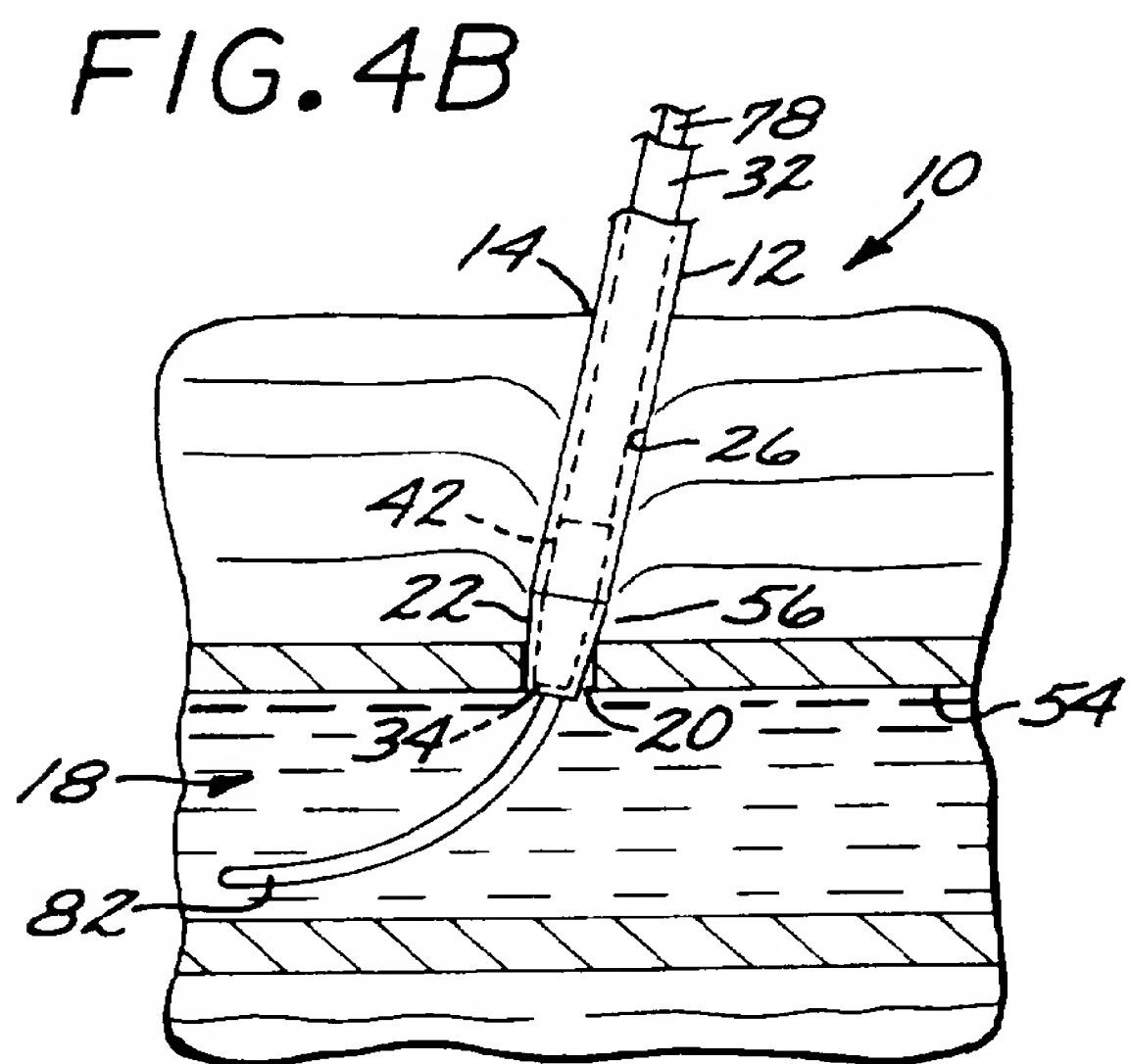
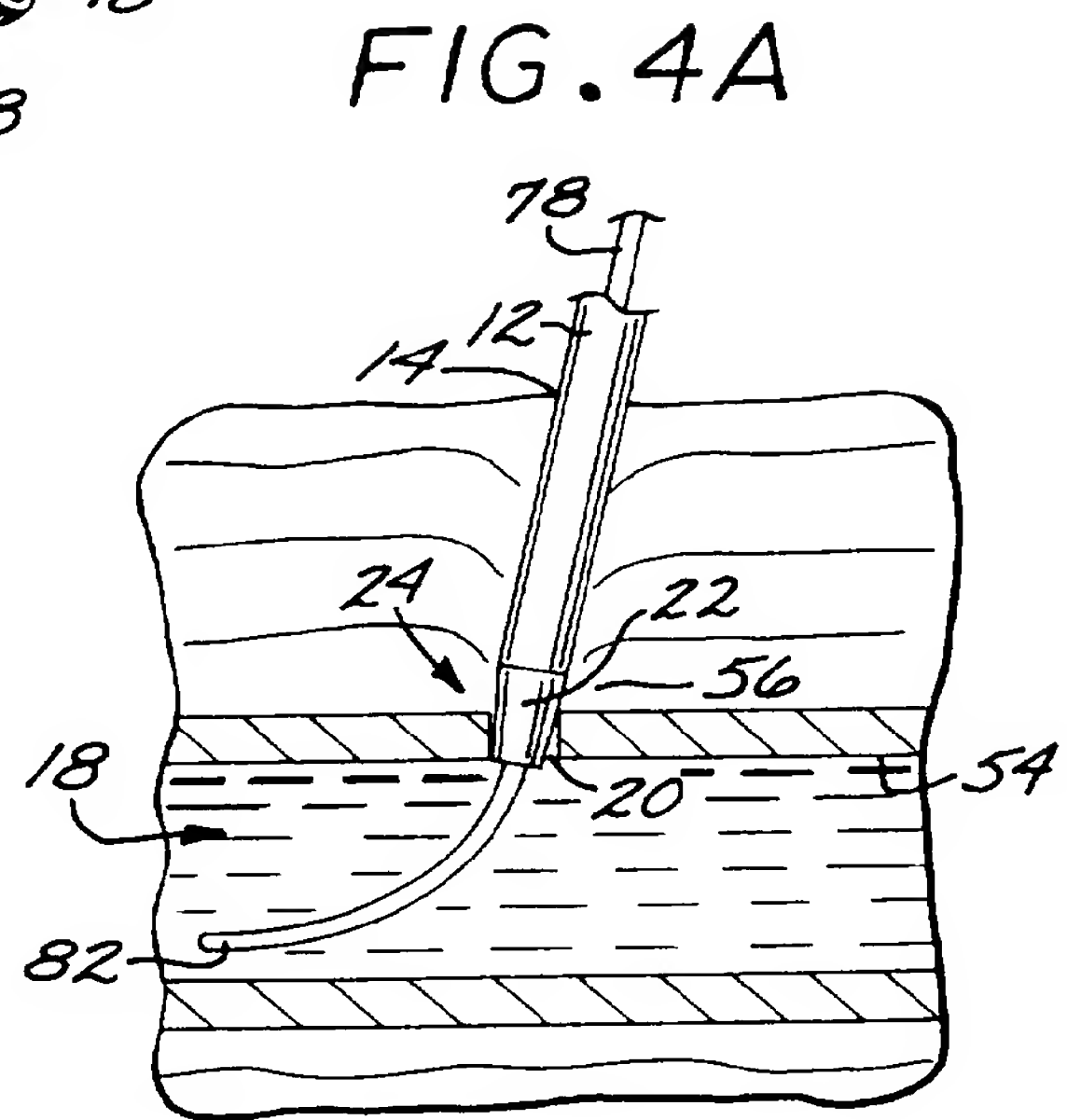
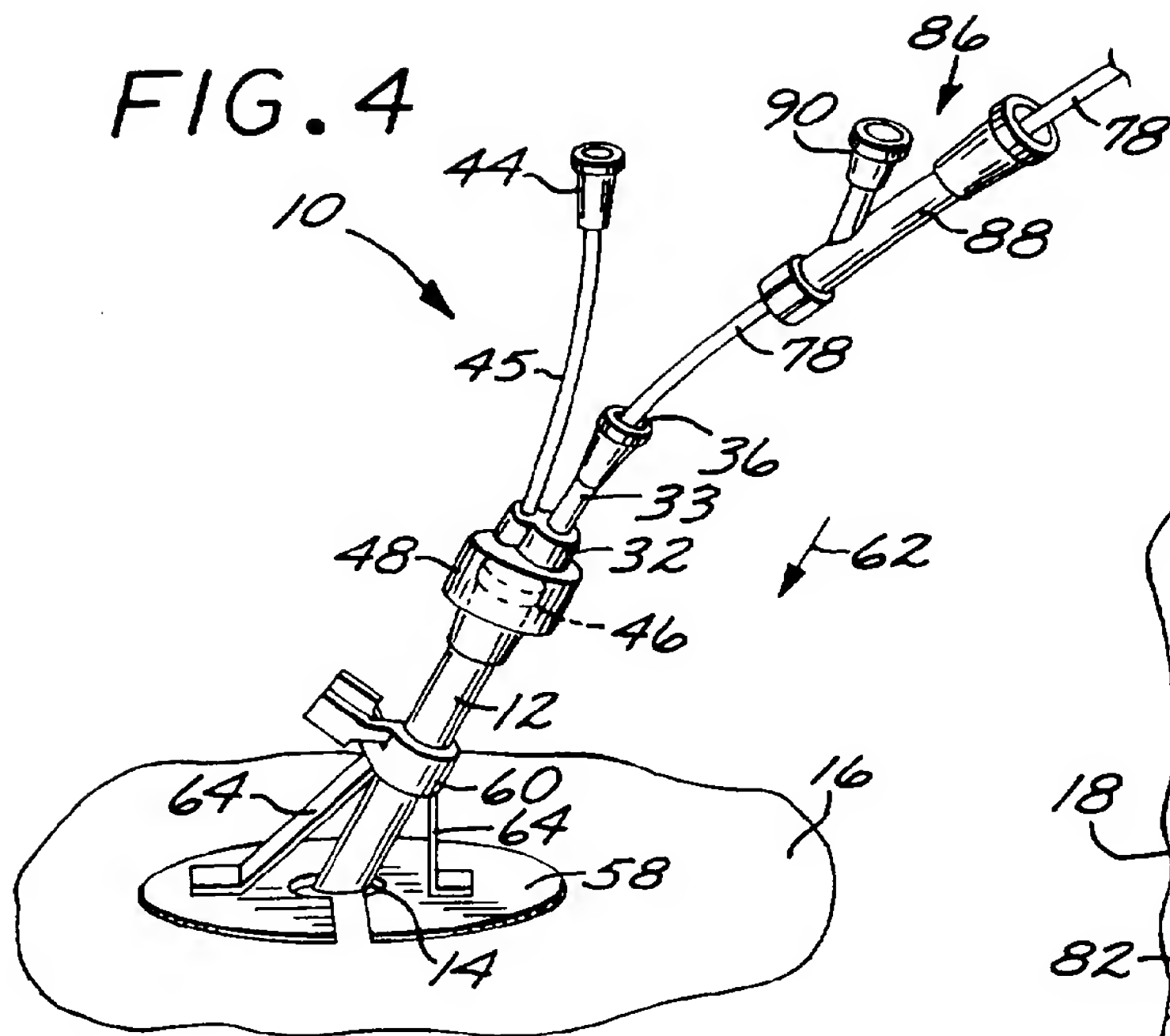


FIG. 4D

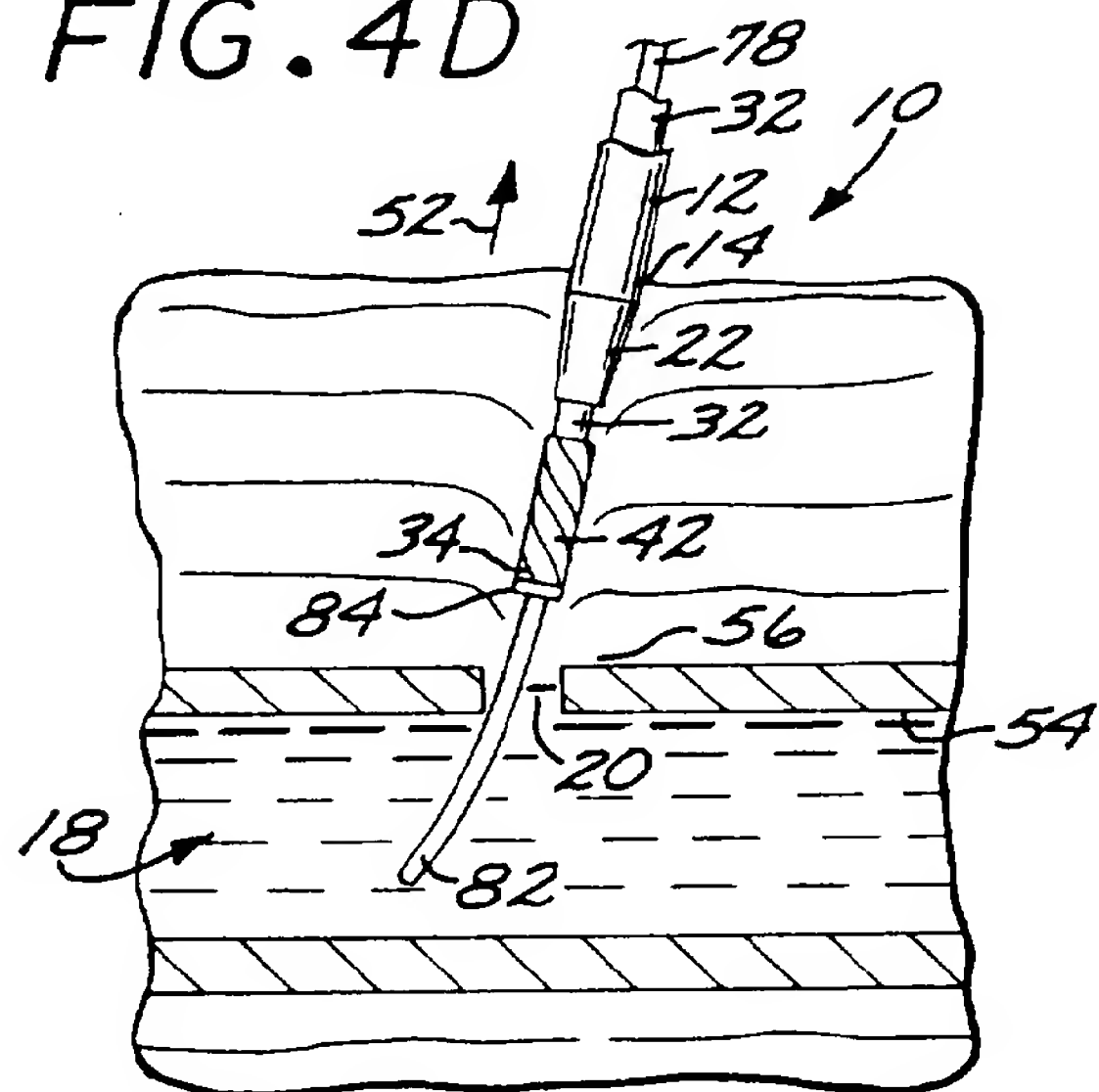


FIG. 4E

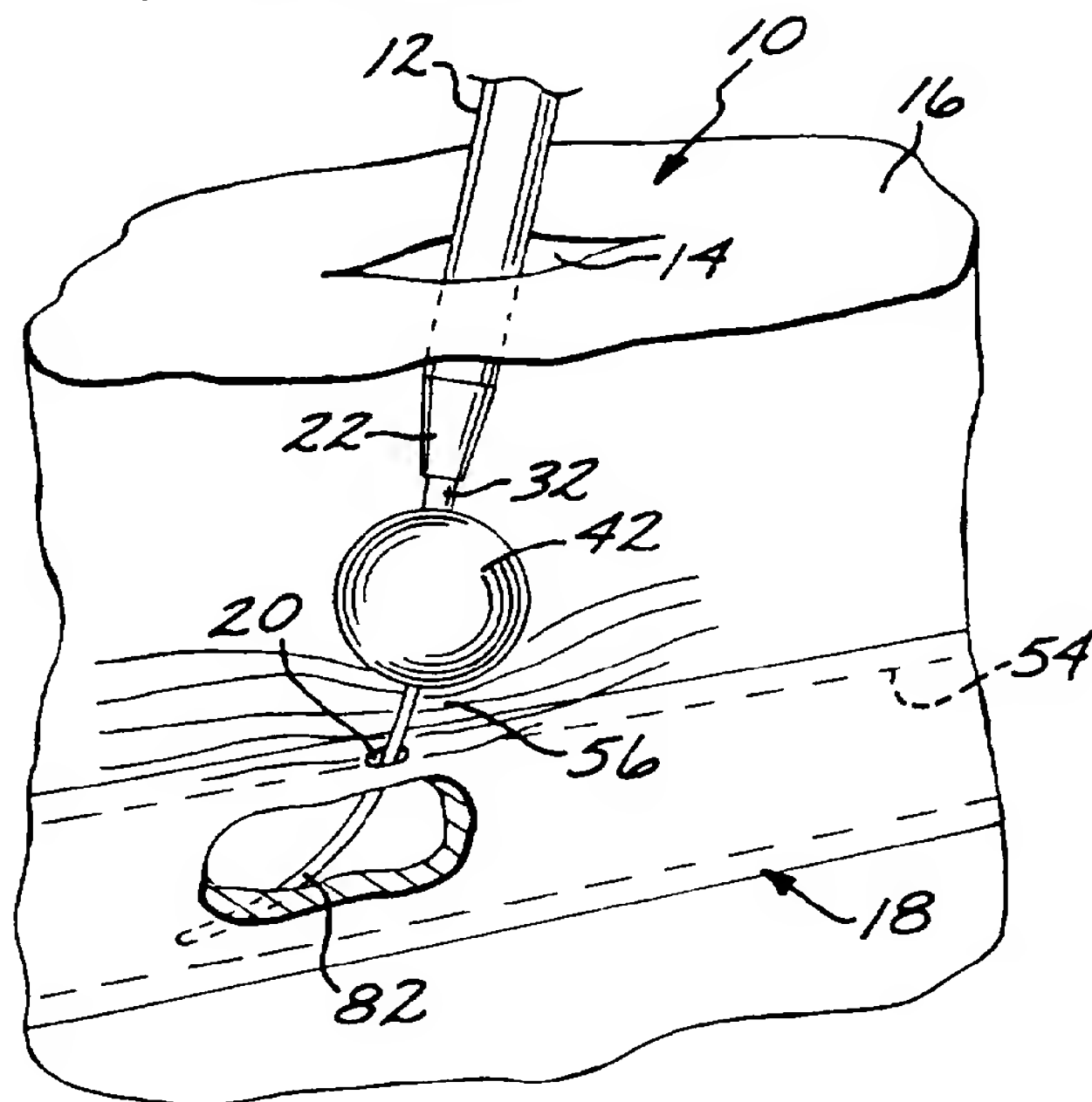


FIG. 4F

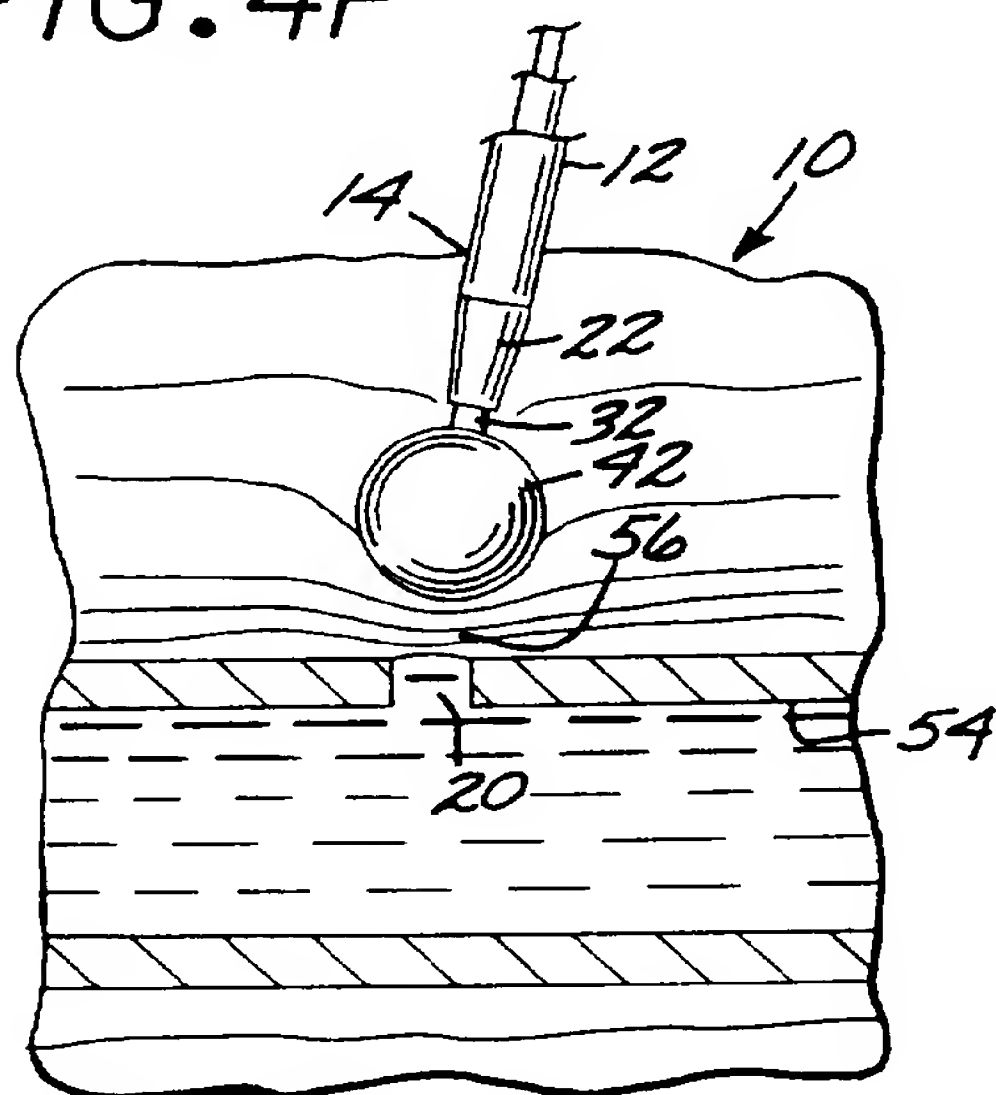
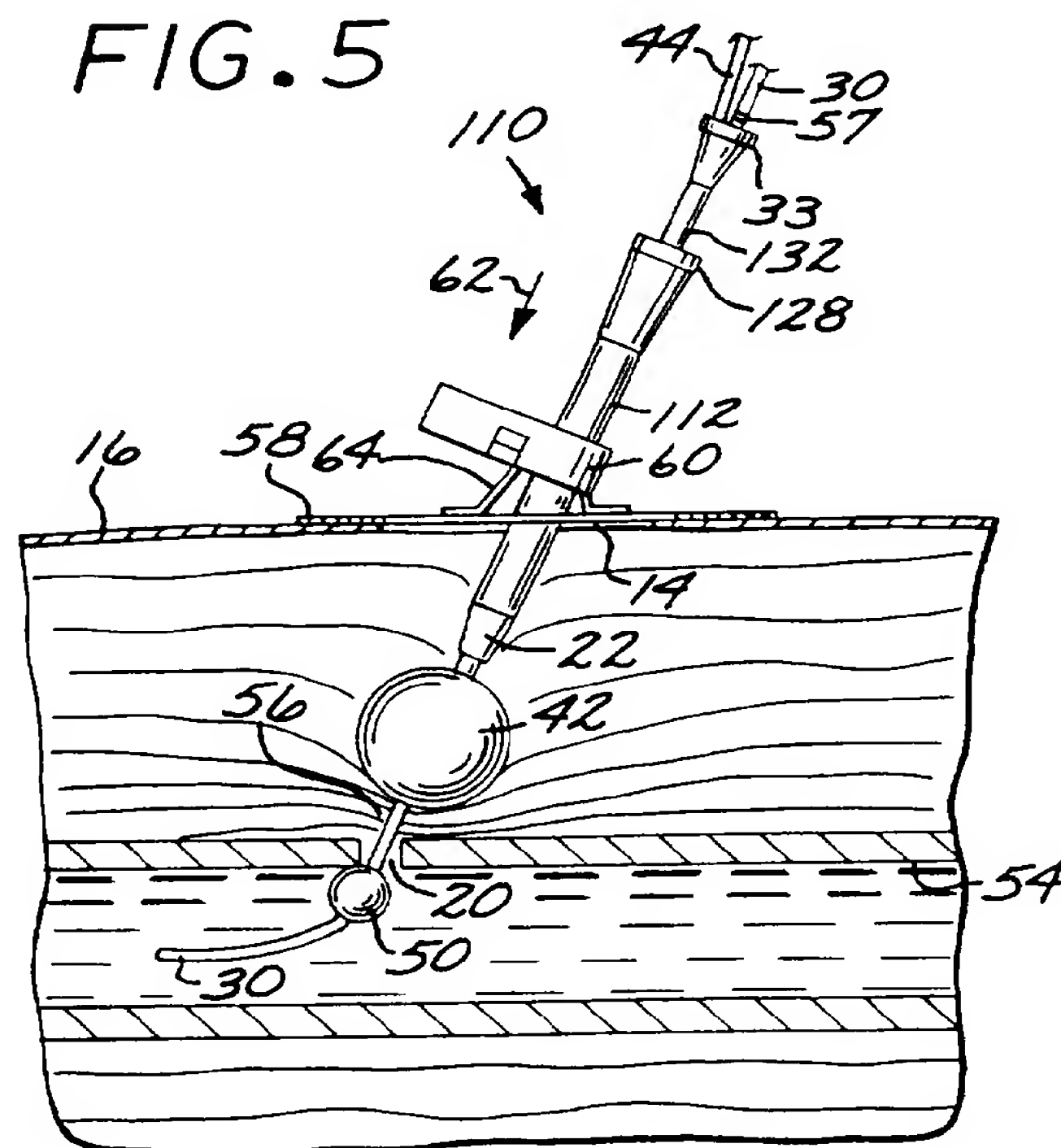


FIG. 5



INTERNATIONAL SEARCH REPORT

Intern. Application No
PCT/US 96/14486

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,94 02072 (SHERWOOD MEDICAL CO ;KATSAROS GEORGES (BE); THOMAS DAVID GRAEME (U) 3 February 1994 see page 6, line 24 - page 7, line 6 see page 11, line 13 - line 16 see page 14, line 23 - line 28 see page 16, line 16 - line 25 see page 22, line 25 - page 23, line 1 see figures 2,7-12	1,2,5,7, 13,14, 20,21, 32,41
X	---	19,23
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

7 January 1997

Date of mailing of the international search report

15. 01. 97

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Fax: (+ 31-70) 340-3016

Authorized officer

Chabus, H

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/14486

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US,A,5 419 765 (WELDON THOMAS D ET AL) 30 May 1995</p> <p>see column 2, line 10 - line 26 see column 6, line 23 - line 33 see column 7, line 7 - line 15 see column 13, line 5 - line 16 see figures 4-13,22A-24D</p> <p style="text-align: center;">---</p>	<p>1,2, 4-16, 19-25, 29-31, 33,34, 37-40, 42,43</p>
A	<p>EP,A,0 637 431 (VODA JAN) 8 February 1995</p> <p>see column 5, line 43 - column 6, line 1 see figures 3-5</p> <p style="text-align: center;">---</p>	<p>17,18, 26,27, 35,36, 44,45</p>
A	<p>EP,A,0 557 963 (UNITED STATES SURGICAL CORP) 1 September 1993</p> <p>see column 4, line 30 - line 49 see column 7, line 26 - line 31 see column 8, line 7 - line 17 see figures 1-5</p> <p style="text-align: center;">-----</p>	<p>3,28</p>

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 96/ 14486

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 46-53
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1(iv) Method for treatm of human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. Application No

PCT/US 96/14486

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-9402072	03-02-94	US-A- 5413571	09-05-95
		AU-A- 4675093	14-02-94
		CA-A- 2140349	03-02-94
		EP-A- 0684788	06-12-95
		JP-T- 8501707	27-02-96
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		JP-A- 7227423	29-08-95
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		US-A- 5405360	11-04-95
